NANCi

NAMIBIA NETWORK OF THE COSMETICS INDUSTRY

GMP Manual

A Guide for

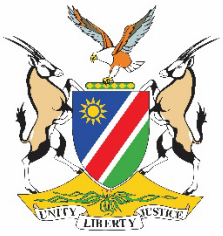
Good Manufacturing Practices

tailored for the Cosmetics Industry

released December 2022

TRADE FORWARD
SOUTHERN AFRICA

HM Government



Implemented by
giz Deutsche Gesellschaft für Internationale Zusammenarbeit(GIZ)GmbH

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Layout and Design: Mr Michael Degé

Foreword for GMP Manual

GMP for the cosmetics sector, is also known as cGMP, are referring to Good Manufacturing Practices, which emphasize the requirements for companies to adopt tools and technologies that are consistent with the standards presently set.

The International Organization for Standardization (ISO) 22716 is a set of comprehensive guidelines for GMP for cosmetics and personal care sector introduced in 2007. Cosmetics refer to the goods or materials intended to enhance, cleanse, or alter a consumer's face or body through makeup, oral care to products such as creams, deodorants, hair products, and fragrances. The ISO is an internationally recognized non-governmental body that sets many standards across a wide range of industries. In 2007, the International Cooperation on Cosmetic Regulations (ICCR), formed by the United States (US), Canada, the European Union (EU), and Japan, determined that this standard would be used when recommending or publishing cosmetic GMP guidelines for each country.

The ISO 22716 good manufacturing practice cosmetics guidelines, therefore, are the criteria of cosmetics GMP when it comes to international standards. In 2009, the EU determined that this standard be used as part of conforming to the EU Cosmetic Regulation 1223/2009. In 2013, the Food and Drug Administration (FDA) in the US published its updated GMP guidelines, considering the recommendations stated in ISO 22716.

When cosmetics and personal care products are commercially placed, whether locally in Namibia, regionally for example in the SADC or for export to the EU, UK and/USA, it is assumed that if these products are sold in these retail markets, the products have been manufactured in compliance with GMP. Conformity by self-assessment and/or third-party verification is acceptable. Compliance to market access requirements is non-negotiable, regardless of size and/or turnover of the manufacturing outlet.

Since the formation of NANCi in 2017, several members are now selling the products in the retail markets, locally, regionally and internationally. Therefore, conformity to market access requirements must be attested. NANCi members have expressed the desire to better understand cGMP and to be enabled to implement these in their SME[1] setting.

The manual is considered easy to implement. Each NANCi user can download the standard operating procedures chapter by chapter, and adjust these to their manufacturing and business situation, including placing their logo on documents, without losing sight of GMP conformity. The manual is also downloadable as one major document. However, in this format, standard operating procedures are then not editable. The manual will be available as an online version only, and persons interested in accessing it can contact NANCi.

NANCi would like to thank the following experts, institutions and development organisations for their firm support towards the establishment of the implementation manual on GMP for the cosmetics and personal sector, tailored to the Namibian manufacturing situation.

[1] The Namibian Ministry of Trade and Industry (MTI) in its SME policy from 1997 defines SMEs as manufacturing companies, employing less than 10 people, reaching a turnover of less than N$1 000 000 and having a capital basis of less than N$500 000.

- Senior Expert Services (SES), Germany for availing a GMP expert to NANCi over a period of one year during 2020/21. Dr Wolfgang Hoederath is equally thanked for his patience and unlimited support working within NANCi member companies and find the most appropriate and practical solution for the implementation of cGMP.

- GIZ ProBATS[2], for facilitating several workshops, ensuring that NANCi members had platforms for exchange to discuss the common challenges and find appropriate solutions. In fact, GIZ ProBATS has been by NANCis side since its conceptualisation and inception. Without GIZ ProBATS, NANCi as an association and its single member companies would not have been enabled to make such great strides in the Namibian cosmetics, health and personal care industry in Namibia, and the SADC-sub region.

- GIZ ProBATS has also availed an intern over a period of six months who assisted in compiling the early draft of this manual. A special thank you to Ms Ghafsa Ryflief, a final year student in B.Sc. Chemistry at the Namibia University of Science and Technology.

- TFSA[3] and the UK Government for availing direct funding to NANCi to hire a layout designer. This enabled NANCi to present the manual in an editable format which eases implementation, especially at SME level.

- NANCi members are thanked for their support and endurance to carry this important milestone to fruition.

Wishing you successful implementation and GMP conformity,

Yours,
Ms Stefanie Huemmer
NANCi Chairperson 2019 - 2022

[2] Gesellschaft für internationale Zusammenarbeit, Promotion of Business Advisory and Economic Transformation Services programme (2010 – 2022)

[3] Trade Forward Southern Africa (2019 – 2023)

Contents of the GMP Manual

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 1,2: Introduction / Common Terms

Standard:	ISO EN 22716: 2007 COSMETICS GMP
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1. Introduction

The ISO 22716 is the Cosmetic Good Manufacturing Practices System (GMP) which forms the foundation of the EU regulations for cosmetics. It acts as a guideline with high constraints to ensure consumer safety and conformity. Cosmetic products manufactured and sold in European countries must be in compliance with the GMP standards defined in ISO 22716. This standard is mandatory in European countries and it is highly recommended in many other countries where an established cosmetic market exists, like Japan, USA, Canada and Korea, to mention a few. To adapt to the global market, most countries see the ISO 22716 as a prerequisite for international sales. The standard encompasses all contributors to the cosmetic manufacturing industry. This includes ingredient manufacturers, distributors, end-product companies as well as importers/exporters.

A producer, regulator or consumer cannot sense (through smell, feel, or see), test (laboratory analysis) or force (penalties and fines) quality or safety into a product. Manufacturing under conditions and practices required by the GMP guidelines or regulations help assure that quality is built into the design and manufacturing process at every step.

In addition to the advantage of competing in the international market, this GMP standard addresses additional issues such as technical and managerial issues. Issues relevant to the human component, which would directly influence the quality of a product, are included. The ISO serves as a guideline through all the phases of production. It improves activity flow and customer satisfaction. If the standard is well incorporated, the product will be considered safe for retail. The standard was put together by industry professionals and promotes the highest methods of class.

The content of this manual is intended to provide guidance regarding GMP (Good Manufacturing Practices). The manual outlines various regulations to be taken into consideration by the cosmetic industry based on the specific requirements of this sector. The manual provides organisational and pragmatic advice on the management of the human, technical and administrative aspects concerning product quality.

The manual was developed to ensure the flow of cosmetic production from receipt to shipment. Each chapter refers to its own integral part to allow the user to easily identify the overall goal pertaining to a particular chapter.

GMP represents the feasible establishment of the quality assurance concept by describing the cosmetic production activities based on firm scientific judgement and risk assessments. The goal of this manual is to outline the measures that need to be taken to obtain a product that meets the GMP standard requirements.

Documentation is a major attribute of Good Manufacturing Practices.

Scope

This International Standard establishes criteria for the manufacture, control, storage and transportation of cosmetics.

These recommendations address product quality, but they do not address worker safety or environmental concerns. It is the company's inherent responsibility to put forward safety and environment practices. However, this may be limited by local legislation and regulation.

Research and development efforts, as well as the distribution of final products, are not covered by these guidelines.

Disclaimer

This guidebook is intended solely for informational purposes. This guidebook is not meant or suggested to be a replacement for professional guidance. Users of this guidebook should consult their professional advisers to determine if the material in this guidebook is appropriate for their specific circumstances.

While the information in this guidebook has been carefully prepared and assembled, the NANCi administration, its employees and agents accept no claims, expressed or implied, as to it's accuracy, adequacy, completeness or reliability. Updates may be obtained at https://nanci.biz/ or by contacting NANCi administration at +264 (0)81-149-1086.

Use restrictions

No one may edit, reformulate, adapt, alter, adjust, change or disassemble this guidebook (with the exception of the templates) or commercially exploit the contents of this guidebook, without NANCi's prior written consent. Requests for approval can be sent to: info@nanci.biz

2. Definition of common terms

Acceptance criteria:	Acceptance of test results based on quantitative limits, ranges or other appropriate measures.
Audit:	Systematic and independent review to establish whether quality activities and related results are in accordance with planned arrangements, and whether these arrangements are effectively implemented and are appropriate for attaining objectives.
Batch:	A predetermined quantity of raw material, packing material or product that is anticipated to be homogeneous after one or more operations.
Batch number:	A unique collection of numbers, letters, and/or symbols that uniquely identifies a batch of products.
Bulk product:	Any product that has gone through all stages of production up to but not including final packing.
Change control:	Internal organisation and duties in relation to any planned change of one or more GMP activities in order to ensure that all manufactured, packaged, regulated and stored products meet the stated acceptance criteria.
Cleaning:	Chemical action, mechanical action, temperature and application duration are all operations that ensure a level of cleanliness and appearance by separating and removing generally visible dirt from a surface using a multitude of resources in variable proportions, such as chemical action, mechanical action, temperature and application duration.

Complaint:	External data suggesting that a product fails to meet predetermined approval criteria.
Contamination:	Occurrence of any undesired substance in the product, such as chemical, physical or microbiological contamination.
Cosmetics:	Any article or substance (except a medicine) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body for purposes of cleansing, beautifying, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance
Contract acceptor:	A person, firm or outside organisation acting on behalf of another person, company or organisation.
Control:	Confirmation that the acceptance criteria have been met.
Deviation:	Internal organisation and duties for deviating from stated standards, due to a planned or unplanned temporary circumstance, involving one or more operations covered by the Good Manufacturing Practices.
Finished product:	A cosmetic product that has gone through all stages of production, including packaging and shipping in its final container.
In-process control:	During production, controls are carried out to monitor and, if necessary, change the process to guarantee that the product fulfils the established acceptance requirements.
Internal audit:	Systematic and independent assessment carried out by competent individuals within the organisation, with the aim to determine whether the operations covered by these rules and related outcomes comply with planned arrangements, are conducted effectively, and are suitable for attaining objectives.
Maintenance:	Any scheduled or unexpected support and verification activities aimed at keeping the premises and equipment in good operational order.
Major equipment:	Equipment that is identified in production and laboratory documentation as being critical to the process.
Manufacturing operation:	A sequence of processes that begins with the weighing of raw materials and ends with the production of a bulk product.
Out-of-specification:	Failure to meet stated acceptability requirements in an inspection, measurement or test result.
Packing operation:	All packaging stages that a bulk product must go through to become a completed product, including filling and labelling.
Packing material:	Any material used in the packaging of a cosmetic product, except transportation outer packaging Note 1: Packaging materials are classified as primary or secondary depending on whether or not they will come into direct contact with the product.
Plant:	Production of cosmetics takes place in this location.

Premises:	Receiving, storage, manufacture, packing, control, and shipment of product, raw materials and packaging materials; physical location, buildings and supporting structures.
Production:	Operations in manufacturing and packaging.
Quality assurance:	All the planned and systematic activities required to ensure that a product meets specified acceptance criteria. QA is a preventative technique, calling for proactive measures. Collectively, the QA department / personnel responsible for QA take charge of all functions relating to delivery of quality goods.
Quality control:	Quality Control: Quality Control is a process that is used to ensure that the activities as per quality assurance programme are being followed correctly. Quality control activities operate and verify that the application meet the defined quality standards. QC is a corrective technique, whereby reactive measures are taken to ensure reinstatement of quality of products delivered.
Raw material:	Any substance that goes into or is used in the production of a bulk product.
Recall:	A company's choice to recall a product batch that has already been released to the market.
Reprocessing:	Re-treatment of all or part of a batch of finished product or bulk product, of undesirable quality, from a defined stage of production, reprocessed so that one or more additional procedures can improve it's quality.
Return:	Returning finished cosmetics to the facility, which may or may not have a quality issue.
Sample:	To gather information about a batch by selecting one or more representative items from that batch.
Sampling:	A number of procedures for collecting and preparing samples.
Sanitisation:	Based on the objectives stated, operation used to eliminate undesired microorganisms on inert polluted surfaces. entry note: It is the process of removing impurities from a surface that are normally unseen.
Shipment:	A collection of procedures for preparing an order and loading it onto a transport vehicle.
Waste:	Any material or product whose possessor plans to dispose of it as a result of a manufacturing operation, transformation or use.

How to use this guidebook

The manual was designed as a general guideline which will assist in managing all the tasks required to meet GMP compliance standards. The checklist provided below comprises of a detailed outline of each GMP requirement, divided into sections and subsections all of which are numbered. The shaded areas within the checklist denote some GMP requirements that may necessitate further application or research. All sections in

the checklist which entail supporting attachments such as templates, forms, or SOP's (Standard Operating Procedures) have been denoted with an asterisk (*). To find the aforementioned attachments simply follow the number and subsequent section title. The SOPs have been numbered according to chapter number and its corresponding grey shaded area in each checklist, following by the SOP title, for e.g. "8.5 Returns: SOP 231-Handling of returned goods" informs the user that the SOP was based on Chapter 8 of section 8.5 in the checklist of the GMP requirement number 231 and the title of the SOP is Handling Of Returned Goods. If there are any annexures or supporting documents referred to in a SOP then it shall be provided directly below the SOP and shall be titled with the sequence – chapter number/SOP Number/Annex (number)/Type of document/ title of document. For e.g. 8. 231.Annex 1: Form - Returned Goods Verification Record'' informs the user that this is a form for "Returned Goods Verification Record", it is the first annexure of the SOP 231 that is referred to in chapter 8 of section 321 of the checklist.

It should be kept in mind that in addition to the numbering provided the manufacturer must ensure that each copy of SOP and the annexure receives a number according their own personal numbering system. This entry shall be made by the manufacturer or appointed staff in the section provided on the document itself. Furthermore, it is worth noting that the documents provided are not specific and were designed to provide users with a simplified guideline, the text is but a mere suggestion and should be personalised to suit each company's own specifications.

Important note

These templates were constructed in Microsoft Word For Microsoft 365 version 2102 because it is currently the most conventional programme for written documents. To use the templates in this guide, you must be acquainted with the Microsoft Word computer programme. They can however, be printed out in hardcopy format for user convenience. Samples of procedures and checklists are provided. Templates must be customised to fit each operation and facility.

How to use these templates

Throughout the electronic version of the templates, bolded fields in brackets (e.g. [XXXXX]) are used. These fields indicate that specific information must be included, allowing you to customise the forms to your specific needs.

Some of the bolded fields may not be applicable to your business. You can leave these out or edit them to match your facility's/operations' needs. You can also add fields (information) that will affect your programme directly. The templates are simply intended to serve as a starting point for creating your own basic cosmetic manufacturing programme. The "navigation pane" in the Microsoft word programme will make it easy to find any specific templates. By typing a title or keyword in the search bar, the document you are searching for can be retrieved.

Need more cosmetic manufacturing information?

Email us on: info@nanci.biz

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NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 3: Personnel

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Chapter 3. Personnel

Introduction

The principle in underlying personnel management in GMP implementation is: adequate appropriately trained personnel to produce, control and store products with a defined quality. Successful cosmetic production as well as compliance with GMP standards such as a good quality control system, a congruent manufacturing structure and active ingredients, all depend on the personnel who operate within this system. It can therefore be deduced that the greatest resource of any company is not its capital, facilities or equipment, but its personnel. A cosmetic company should ensure that they employ qualified key personnel and staff who are trained in the principles and application of GMP to ensure:

- the health of all personnel
- that the product is protected from contamination
- the preservation of product quality.

Personnel are an essential element of GMP implementation. Personnel management involves obtaining, retaining and developing satisfied employees. This includes maintaining fair terms and conditions of employment, managing personnel activities and keeping relevant records. This also comprises developing and implementing policies and processes to create an orderly, employee-supportive workplace.

Objective

The main purpose of this chapter is to facilitate an in-depth understanding of the requirements for personnel in manufacturing facilities of cosmetic companies. In addition, the information on the organisational structure of the company is available.

Scope

This thematic area of the GMP standard applies to all personnel in the cosmetic manufacturing company, such as quality control, warehouse, manufacturing, packaging and other.

Organisation

As already mentioned, the establishment and maintenance of a satisfactory system of QA, QC (Quality Control and Assurance) and manufacturing cosmetic products rely on people. It is imperative therefore that there are qualified personnel to carry out tasks. In addition, individual responsibilities must be clearly understood by the staff concerned, and all personnel should be aware of the principles of cosmetic GMP as required. Training, which also includes instructions on hygiene relevant to their needs, must be made available. Personnel should be experienced with relevant procedures, processes and equipment. An organisational chart with a clear organisational structure should be available. The structure should be complete. The organisational chart will outline the key personnel within the company and the individuals who work under them. Key personnel usually work full time; that would be the Head of Production (HOP) and Head of Quality Control and Assurance (QA). Quality Control (QA) and Head of Production (HOP) are completely independent of each other. In a small organisation, it should be possible that one operator is responsible for manufacture and another one for QC. By SOP, they should be independent in these functions, even though by hierarchy one is subordinate to the other. For different products/batches it is possible for them to change responsibility.

The organisational structure should be:

- defined, that is established
- appropriate for the size of the company
- appropriate to diversity of its products.

The organisational structure should be such that:

- the organisation of the staff is understood
- the functioning of the staff is understood
- the quality unit(s) is/are independent of production

The number of staff should be adequate to the:

- scope of activity for example, full scale production, manufacturing only, laboratory or packaging only (compare subcontracted work)
- diversity of production
- defined activities in these guidelines

Key responsibilities

Individuals should have a clear understanding of the organisational structure of the company. They should be briefed on their individual responsibilities, the unauthorised access points within the facility and they should be informed about personal hygiene standards. Staff should also be made aware of protocols in relation to handling any deviations on responsibilities. Adequate training should also be provided for every position. All job descriptions and training should be properly documented and accessible to all personnel.

Responsibilities of the HOP are as follows:

- Product production and storage according to required documentation
- Approval and implementation of production instructions, in-process QC and ensuring strict implementation
- Evaluating production records; approval before passing to QC
- Maintenance of production department, premises and equipment
- Performance calibration, recorded and reporting
- Training of production personnel; initial and on-going.

Responsibilities of the QC are as follows:

- Approval or rejection of materials, packing materials, intermediates, bulk and finished products
- Evaluation of batch records
- Testing
- Approval of quality control procedures such as sampling instructions, specifications, test methods and other QC procedures
- Approval and monitoring of all contract analysis
- Maintenance of quality laboratory, including equipment and laboratory apparatus
- Calibration of control equipment
- Initial and continuous training of QC personnel.

Training

To produce cosmetics, it is important that staff have the correct skills to delegate tasks efficiently for all processes to run smoothly and cost-effectively. Therefore, a well-established training programme should be provided to all individuals. The courses should be tailored to the jobs, with special focus on the newly hired personnel. This includes GMP-training and training for duties as required. It should be ensured that training, whether conducted internally or by an external organisation, is continuous and updated on a regular basis. The training programme is documented, and the accumulated knowledge evaluated after the training. The

training will include all personnel whose duties take them into production or control laboratories. However, all staff who are responsible for the quality of a product should be well-trained. The programme will focus on induction, on-going training and on theory and practice of GMP. The programme will be approved by either the Head of Production (HOD) or QC, as appropriate. The training records are filed, and training should be provided before undertaking any new tasks.

Personnel hygiene and health

The GMP standard contains an assurance that all products produced are of equivalent consistency and quality. For that reason, it is important to avoid any cross-contamination in the cosmetic manufacturing process. Hence, a well-established hygiene programme should be followed by everybody in production, QC, and in warehouse facilities. All hygiene rules associated with each area must be strictly implemented. Hands must be regularly washed, and appropriate clothing must always be worn. No consumption of food, drinks, or medicine in any of the cosmetic production areas is allowed. Smoking and chewing in all manufacturing areas is prohibited. Direct contact with products including packaging materials by unprotected operator's hands must be always avoided. Clean clothes should be worn daily.

Visitors and untrained personnel

To maintain and uphold the company's principle of hygiene and to prevent cross-contamination, it is vital that visitors and untrained personnel are informed of all directives in advance. This includes personal hygiene and protective clothing requirements. In addition, visitors and untrained personnel must always be accompanied and supervised by company personnel. Documentation of visitors and untrained personnel should be kept and authorised.

Chapter 3: Personnel checklist

Guidance for compliance: Chapter 3 - Personnel							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	3.	**Personnel**					
	3.1	**Principle**					
	3.2	**Organisation**					
	3.2.1	**Organisation chart**					
1*	3.2.1.1	Is an updated organisational chart available, which is comprehensible and appropriate for the size of the company and the diversity of its products?					
2	3.2.1.2	Are adequate staffing levels available according to the respective production in the individual fields of activity?					
3	3.2.1.3	Does the organisational chart show the independence of the quality unit (quality assurance / quality control) from the other units of the plant?					
	3.2.2	**Is trained personnel with regard to the activities defined in these guidelines available:**					
4	3.2.2a	- in the field of production?					
5	3.2.2b	- in the field of quality control?					
6	3.2.2c	- in the field of purchasing / procurement?					
7	3.2.2d	- in the field of gateway / incoming goods?					
	3.3	**Key Responsibilities**					
	3.3.1	**Management responsibilities**					
8	3.3.1.1	Is the organisation supported by the top management of the company?					
9	3.3.1.2a	Does the responsibility for the implementation of Good Manufacturing Practices lie with the top management?					
10	3.3.1.2b	Does the top management involve the personnel of all departments and positions of the company in the implementation of Good Manufacturing Practices?					
11	76/768/EC	Does the Head of Manufacturing have a basic scientific or technical education?					
12	76/768/EC	Does the Head of Quality Control have a basic scientific or technical education?					
13	3.3.1.3	Are the areas in the manufacturing plant, which may only be accessed by authorised personnel, defined?					
	3.3.2	**Responsibilities of Personnel**					

Guidance for compliance: Chapter 3 - Personnel							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
14	3.3.2a	Do the personnel know their position in the organisational structure?					
15	3.3.2b	Do the personnel know their defined responsibilities and activities?					
16	3.3.2c	Do the personnel have access to the documents which are relevant for their particular scope of responsibility?					
17	3.3.2d	Are the provisions of the documents in the respective scopes of responsibility complied with?					
18	3.3.2e	Do personnel comply with personal hygiene requirements?					
19	3.3.2f	Do personnel report irregularities or non-conformities within their scope of responsibility?					
20	3.3.2g	Do personnel have adequate education, training and/or skills to perform the assigned responsibilities and activities?					
	3.4	**Training**					
	3.4.1	**Training and Skills**					
	3.4.2	**Training and Good Manufacturing Practices**					
21*	3.4.2.1	Is the personnel offered appropriate training in Good Manufacturing Practices?					
22	3.4.2.2a	Are the training needs of all personnel determined?					
23	3.4.2.2b	Is a training programme developed and implemented based on the identified training needs?					
24	3.4.2.2c	Is the training programme documented?					
25	3.4.2.3	Are the training courses for the respective personnel appropriate to the jobs and responsibilities of individuals considering their expertise and experience?					
26	3.4.2.4	Are the training courses developed and implemented by internal or external personnel?					
27	3.4.2.5a	Are trainings carried out on a regular basis and adjusted to current circumstances?					
28	3.4.2.5b	Is documentation done on trainings carried out?					
29	3.4.3	Is newly recruited personnel trained on the theory and practice of Good Manufacturing Practices as well as training appropriate to the duties assigned to it?					

Guidance for compliance: Chapter 3 - Personnel							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
30	3.4.4	Is the knowledge accumulated by personnel evaluated during or after training?					
	3.5	**Personnel Hygiene and Health**					
	3.5.1	**Personnel Hygiene**					
31*	3.5.1.1a	Has a hygiene programme been established for the production, quality control and storage areas?					
32	3.5.1.1b	Has the hygiene programme been adapted to the needs of the plant?					
33	3.5.1.1c	Are the requirements defined in the hygiene programme understood and followed?					
34	3.5.1.2a	Are sufficient facilities for hand washing and hand disinfection available?					
35	3.5.1.2b	Has the personnel been instructed in respect of hand washing and disinfection?					
36	3.5.1.2c	Are the facilities for hand washing and disinfection used?					
37	3.5.1.3a	Do personnel wear appropriate clothing and protective garments to avoid contamination of cosmetic products?					
38	3.5.1.3b	Does the quality control personnel wear appropriate and prescribed clothing and protective garments to avoid contamination of cosmetic products?					
39	3.5.1.3c	Does the warehouse personnel wear appropriate and prescribed clothing and protective garments to avoid contamination of the cosmetic products?					
40	3.5.1.4a	Is there a ban in place on eating and drinking, chewing and smoking in the production, quality control and storage areas?					
41	3.5.1.4b	Is there a ban in place on storing food, drink or smoking materials or personal medication in the production, quality control and storage areas?					
42	3.5.1.4c	Is there provision in the production, quality control and storage areas concerning the directives for wearing of a watch and any jewellery (including a wedding ring), artificial fingernails and visible piercings, etc?					

Guidance for compliance: Chapter 3 - Personnel							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
43	3.5.1.5	Are instructions in place in the production, quality control and storage areas concerning any unhygienic practice that may arise, to avoid the product from being adversely affected?					
	3.5.2	**Personnel Health**					
44	3.5.2	Have steps been taken to avoid that any person affected by an illness or having open lesions is excluded from the area of open products?					
	3.6	**Visitors and Untrained Personnel**					
45	3.6a	Are visitors and untrained personnel kept away from the production, quality control and storage areas?					
46	3.6b	If visitors need to access the production, quality control and storage areas, are these visitors given the necessary information and are they supervised in terms of personal hygiene and the prescribed protective clothing?					
47	3.6c	Are instructions for the conduct of visitors and third-party handicrafts in the production and storage areas available?					
Reference IKW Cosmetics GMP based on ISO 22716							
Reference Websites A WHO guide to good manufacturing practice (GMP) requirements https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1 Last viewed 13 September 2021 ASEAN Cosmetic GMP Team: https://asean.org/storage/2012/10/ASEAN-TMHS-GMP-Training-Chapter-2-Personnel-FD1.pdf Last viewed 13 September 2021							

3.01.SOP 001 – Organisation of company employees

Logo	**Standard format for SOP:** Organisation of company employees Department: _____ Policy No: _____

Company header: _____

Policy: _____

Organisation of company employees' programme

Name of area: _____ Page: _____ of_____

SOP number _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Purpose:

To lay down the procedure for the organisational set up of the company.

Scope:

This SOP shall be applicable …

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

- All Department Heads

Accountability:

- Head Of Quality Assurance

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. The company is required to set up an organisational chart outlining the individual job titles and job description of all key personnel.
2. The number of staffing levels and employees should be compatible to the size of the company and the diversity of the products manufactured at the company.
3. The chart should clearly distinguish between the individual roles. More specifically the Quality Assurance and Quality Control departments must clearly be segregated and independent from the other units within the company.
4. Although the organisation structure may differ from one company to another, Annexures 1 and 2 below are sample templates of Organisation charts to provide some guidance.
5. Top management defines
   a. the diversity of production
   b. scope of activities
   c. key roles and responsibilities

d. interdependencies
e. number of staff required.

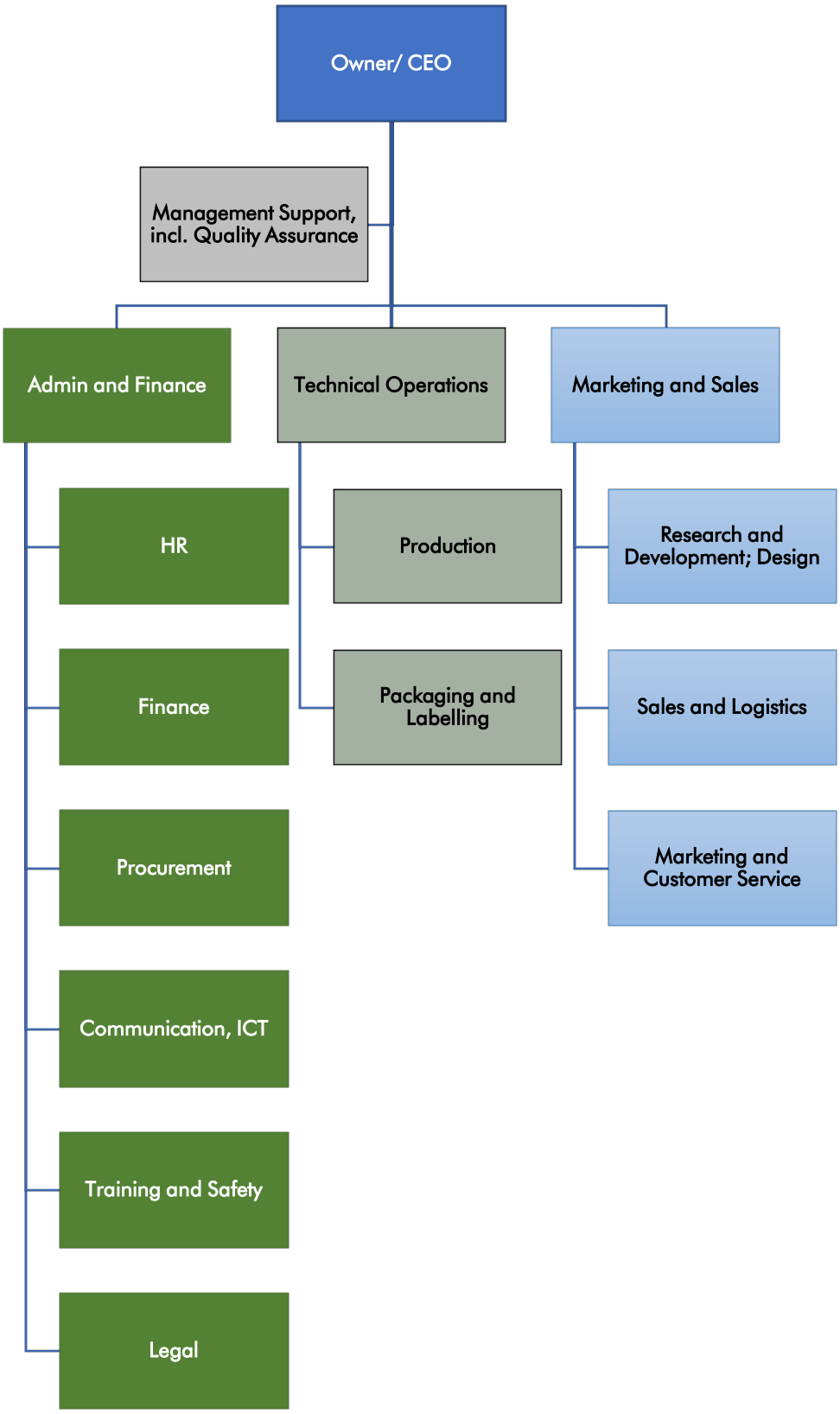
6. Top management to define an organisational chart (see Annex A) to show:
   a. position for each staff
   b. reporting relationships including supervisor (team leader)/supervisee (teams).
7. Top management to define job descriptions (see template in Annex B) for all staff.
8. Communicate organisational chart and job descriptions for all staff including their supervisory roles and supervisees roles.

Reference Documents:

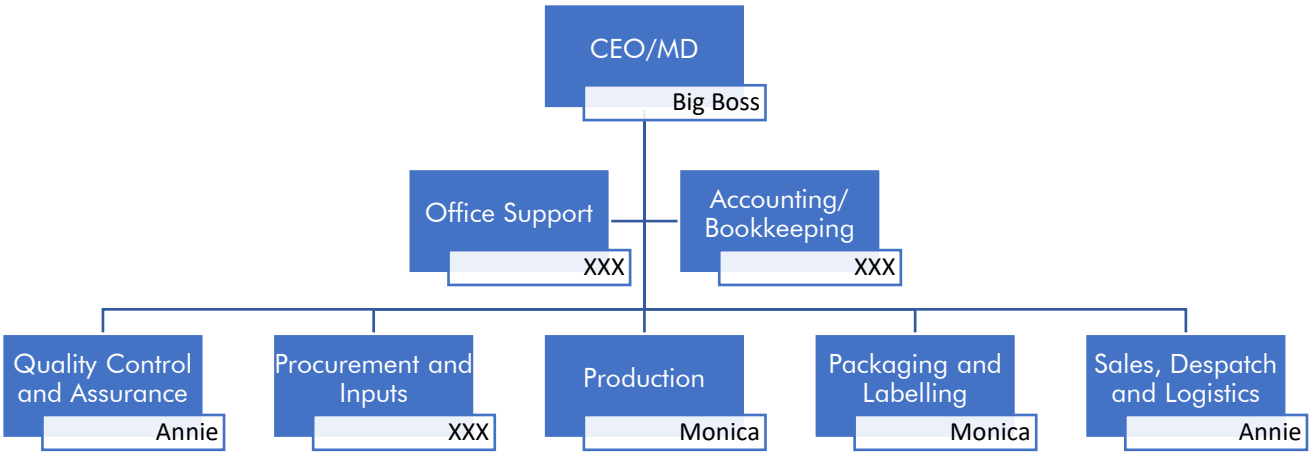
3.01.001 Annex 1: Flowchart - Organisation Chart sample

3.01.001 Annex 2: Flowchart #2 – Organisation Chart sample

3.01.001 Annex 1: Flowchart - Organisation Chart sample



3.01.001 Annexure 2: Flowchart #2 - Organisation Chart sample



3.4.SOP 21 - Training programme

This ensures that your products are manufactured in a clean, hygienic environment and no contamination of your products occur. (Sample of format for sop training programme)

Logo	**Standard format for SOP: Training programme** Department: _____ Policy No: _____

Company header: _____

Policy: All personnel should receive adequate training in Good Manufacturing Practices, health and hygiene and job skills. A training program should be developed and implemented based on the identified training needs.

Organisation of company employees' programme

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Purpose:

WHY: [Why is this procedure written.]

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility

WHO: [Include who performs the procedure, who is responsible to see it is performed correctly?]

Material and equipment:

WHAT: [Include what is needed to perform the test. The list should be complete and specific.]

Procedure:

How: Clear and concise step by step instructions on how to perform the procedure. This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included, if necessary.

It should include:

- Preliminary steps that must be done before beginning the actual procedure.
- Safety considerations: Precautions for work with physical, chemical, or biological hazards
- (Containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
- Use chronological instructions. It is useful to number the steps so that repeat steps can be referred to rather than making the SOP very long.

Calculations: should include explanations and sample of how to do any required calculations.

Reporting:

[WHAT NEXT:]

- Indicate where the results should be recorded.
- Explain what to do if there are problems during the test.
- Indicate that deviations to the procedure must be approved and recorded.
- Identify the person to whom the final results should be reported.

Reference documents:

3.4. 21. Annex 1: Form - GMP Training Record

3.4.21. Annex 2: Chart - Training plan

List other SOPs which directly affect or are relevant to this procedure. For example, the SOP for making a buffer used in the procedure, or the SOP for the operation of a piece of equipment used in the procedure.

3.4.21 Annex 1: Form - GMP training record

Personnel Training Record	
Logo	Company header: _____ Policy: _____

Trainer:	Date:
Training done:	Signature of trainer:

Material presented:

(Specify training materials, ex: policy/procedures, demonstrations, videos, presentations etc.)

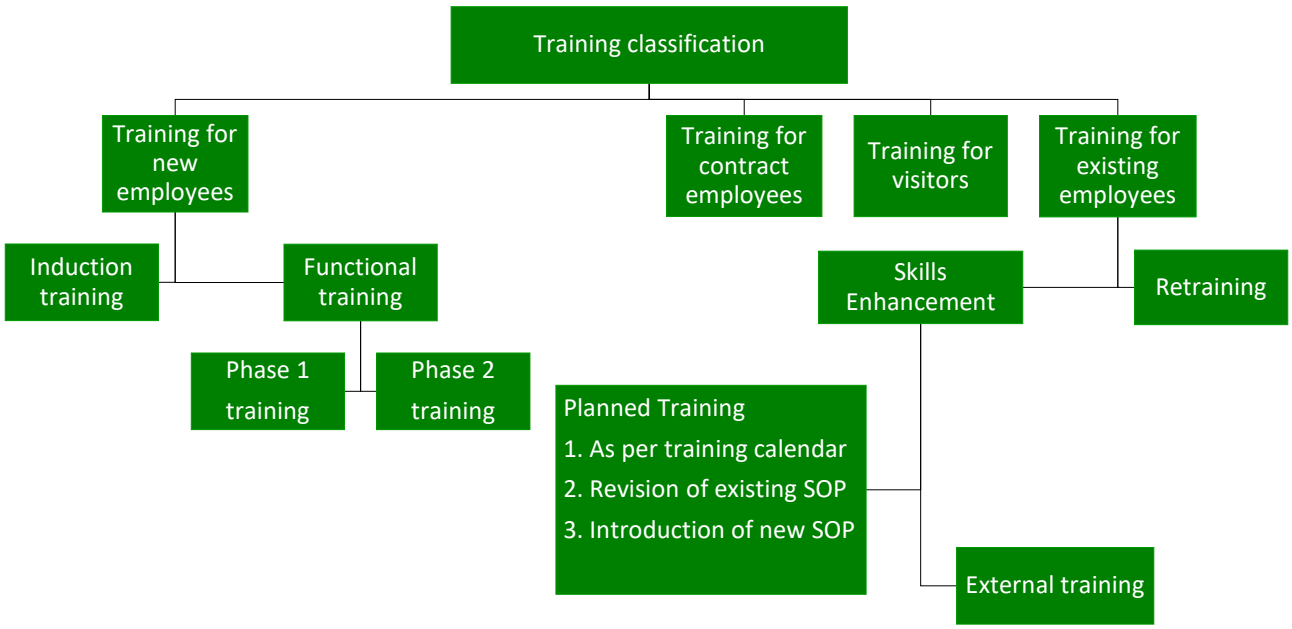
Employee name:	Employee signature:

*The employee signature indicates they have received and understood the information presented and will comply with the policies or procedures.

Date prepared: Authorised by:

(date the policy was prepared/revised) (manager responsible).

3.4.21. Annex 2: Chart - Training plan



3.5. SOP 31 – Health and personal hygiene programme

Logo	**Standard format for SOP:** Health and Personal Hygiene Programme Department: _____ Policy No: _____

Company header: _____

Policy: All cosmetic service employees will maintain good personal hygiene practices to eliminate cross contamination and to avoid the product from being adversely affected.

Health and Personal Hygiene Programme

Name of area: _____ Page: _____of _____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Purpose:

To lay down the procedure ...

Scope:

This SOP shall be applicable …

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Include who performs the procedure, who is responsible to see it is performed correctly.

The unit supervisor will:

- Ensure employees are following proper hygiene requirements when they report to work.
- Follow-up when necessary.

Accountability:

Include who performs the procedure, who will be held accountable to see it is performed correctly.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. **Grooming:**

   1.1. Arrive at work clean – clean hair, teeth brushed, washed, use deodorant daily.

   1.2. Maintain short, clean, and polish-free fingernails. No artificial nails are permitted in the cosmetic production area.

   1.3. Thoroughly wash hands and under fingernails up to forearms with soap and warm water for a period of 20 seconds:

   - When entering the facility before work begins.
   - Immediately before preparing cosmetic ingredients or handling equipment.
   - As often as necessary during the production process when contamination occurs.
   - In the restroom after toilet use and when you return to your workstation.
   - When switching between working with raw materials or when switching between stages during the manufacturing process.
   - After touching face, nose, hair or any other body part, and after sneezing or coughing.
   - After cleaning duties.
   - Between each task performed and before wearing disposable gloves.
   - After smoking, eating or drinking.
   - Any other time an unsanitary task has been performed – i.e., disposing of garbage, handling cleaning chemicals, sanitising workstations.

   1.4. Wash hands only in hand sinks designated for that purpose.

   1.5. Dry hands with single use towels. Turn off taps using a paper towel, to prevent recontamination of clean hands.

2. **Proper Attire:**

   2.1. Wear the prescribed clothing and protective garments – clean factory overall with sleeves and clean close-toed work shoes that are comfortable and non-slippery.

   2.2. Wear factory issued lab coats/garments, as appropriate.

   - Do not wear lab coats to and from work.
   - Take off lab coat before using the restroom.
   - Change lab coat if it becomes soiled or stained.

   2.3. Wear disposable gloves if you have any cuts, sores, rashes or lesions.

   2.4. Wear gloves when handling any open products that could be easily contaminated during the manufacturing process.

   2.5. Change disposable gloves as often as handwashing is required. Wash hands before donning and after discarding gloves.

3. **Hair Restraints and Jewellery:**

   3.1. Hair net or bonnet should be properly worn in any of the designated production, quality control and storage areas. All hair should be completely covered.

   3.2. Keep beards and moustaches neat and trimmed.

   3.3. Refrain from wearing jewellery in the production, quality control and storage areas.

   - Only a plain wedding band is allowed.
   - No necklaces, bracelets, watches or dangling jewellery are permitted.
   - No earrings or piercings that can be removed are permitted.

4. **Illness: (detailed numbered steps and rules)**

   4.1. Report any flu-like symptoms, diarrhoea, and/or nausea to the unit supervisor.

   4.2. Employees with these symptoms shall be sent home. Where symptoms are known to be from a non-infectious condition, exceptions may be taken.

   4.3. Employees could be re-assigned to other activities within the company so that there is no risk of transmitting a disease through cosmetic product contamination.

4.4. Instances of Norovirus, Hepatitis A, Salmonella Typhi, Shigella or Shiga toxin-producing Escherichia Coli must be reported to the unit supervisor.

4.5. If the employee is diagnosed with an infection from Norovirus, Hepatitis A, Salmonella Typhi Shigella or Shiga toxin-producing Escherichia Coli, a decision should be made to prevent product contamination.

5. **Cuts, abrasions and burns:**

5.1. Dress any open wounds i.e., cuts, abrasion or burns which have resulted in broken skin with a clean bandage.

5.2. Cover bandages on hands with gloves and finger cots and change regularly.

5.3. Report all injuries to the unit supervisor.

6. **Smoking, eating and chewing gum:**

6.1. Smoke only in designated areas. No smoking or chewing tobacco shall occur inside production facilities.

6.2. Eat and drink in designated areas only. No food or drink is allowed in the production, quality control and storage areas.

6.3. Refrain from chewing gum or eating candy in any of the production, quality control and storage areas.

6.4. The use and storage of personal medication will not be allowed in any of the production, quality control and storage areas.

Policy last revised on: _____

Definitions:

Reference Documents:

List other SOPs which directly affect or are relevant to this procedure. For example, the SOP for making a buffer used in the procedure, or the SOP for the operation of a piece of equipment used in the procedure.

4

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 4: Premises/Production Plan

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
Document No.:	NANCi-GMP-4- 00
Date of Issue:	30 November 2022

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	Prepared by	Reviewed	Approved by

Signature:

Document change record

No.	Page	Rev.	Date	Details of change

Document revision record

No.:	Document change number:	Author:	Effective date:	Remarks:

Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

Table of Contents

Chapter 4 Premises/Production Plan

Introduction

To avoid cross-contamination and minimise any possible error, a compatible building layout, location and design is required. This should cover all aspects of manufacture, filling and packaging. Additionally, the structure of the facility should be conducive to an effective maintenance and cleaning system. This will impede the build-up of dust, dirt or any possible contaminant which could affect the product.

Objective

There are two main Objectives that should be obtained by this chapter:

- To outline the demarcated area which will be used for the manufacturing process. It should be located, designed, built and maintained in such a way that the manufacturing, personnel and material flow are at minimal risk of contamination.
- To classify and pinpoint the correct materials for effective cleaning, which will minimise the build-up of dirt or other conditions that may directly or indirectly affect the quality of products during their manufacture or storage.

Scope

This chapter applies to all premises related to the production of cosmetic and non-hazardous household products.

Principle

This will ensure the protection of the product, permit efficient cleaning, sanitising, maintenance and minimise the risk of mix-ups of products, raw materials, and packaging materials. Design should be based on the type of cosmetic product that is to be manufactured. In addition to that, the facilities should be designed to have a logical flow of materials and people. It should also allow the adequacy of a proper working space and orderly and logical positioning of equipment, as well as smooth/crack-free/easy to clean interior surfaces. The manufacture of cosmetics should be separated from the manufacture of other products (e.g. drugs, devices). However, non-hazardous household products can be located in a shared premise, provided that extra caution be taken to avoid cross-contamination and risk of mix-up. The segregation of the demarcated areas can be done with the use of painted lines, plastic curtains, or any flexible barrier.

Avoid locating premises in or near areas such as open sewage, drain, public lavatory or other factories producing disagreeable or harmful fumes, odour, dust and smoke, chemical or biological emission.

The following aspects need to be considered when choosing a site:

- ease of access for staff (public transport, distance down an access road)
- finished products, quality of road access (all year, dry season only, potholes that may cause damage to products, especially when glass containers are used)
- availability of infrastructural facilities such as, water, public utilities, civil amenities
- nearby swamp land that would be a source of smells and insects

- any potential contamination of water supplies upstream of the processing site
- available land for waste disposal away from the building
- cleared land to reduce problems caused by insects and birds (preferably planted with short grass, which acts as a dust trap for airborne dust).

Types of area

As mentioned before, a cosmetic manufacturing facility should have clear, well-defined areas for storage production, quality control, ancillary, washing and toilets. Within each area, there should be sufficient space for all operations. The building should host a system that will guide the flow of personnel, materials, and products in a sensible manner that will prevent mix-ups. More specifically, the demarcated areas should include the following:

- Receiving of starting and packaging material
- Sampling
- Weighing/dispensing
- Gowning/ change room
- Storage areas for approved raw material, packaging materials and finished goods
- Quarantine and reject areas
- Processing
- QC laboratory
- Equipment washing
- Storage of idle, cleaned equipment
- Staging of bulk products
- Packaging/ labelling operations
- Storage of cleaning tools and supplies

Space

The demarcated area should be spacious enough for the appropriate operations to be carried out safely. The areas should be designed in such a manner to minimise mix-ups and product contamination, yet optimise maintenance, repair and sanitation procedures. Rest rooms for washing and toilet purposes should be easily accessible and appropriate for the number of users. Toilets should not directly open to production or storage areas.

Maintenance workshops should be as far as possible from production areas.

Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.

Flow

The flow of material and personnel in the manufacturing plant should be well-defined and complied with. This can be done with a simple structural floor plan, with labelled and numbered areas. The floor plan provided is compatible for a simple cosmetic manufacturing facility, designed so that areas may easily be moved, labelled and numbered in Microsoft Word. The flow of personnel and material can be marked/adjusted by means of arrows.

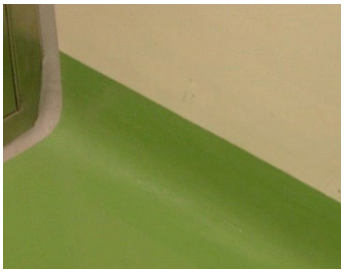
Floors, walls, ceilings, windows

All new production areas should be built in such a way that they can be easily cleaned (smooth surfaces) and consistent against corrosive cleaning and sanitising agents. The floors, walls, ceilings and windows of every area should be structurally planned in such a way to enable easy cleaning, sanitation and repairs. Solid concrete floors are most suitable for a warehouse and epoxy or polyurethane resin floor finish is most suitable for processing areas. However, other materials such as floor tiles are allowed but will have to adhere to the cleaning and sanitising procedures mentioned above. Wood is not a suitable flooring material for cosmetics manufacturing area since it absorbs moisture. Materials used to finish floors may be subject to what is available locally, but requirements must be met. The images provided below are examples of floor finishes that could be used to comply with GMP standards.

Ideally, walls should be of high-density material, smoothly plastered and waterproofed by painting with acrylic or high polymer enamel. The ceiling could be cement boards. Ceilings should be weather resistant, termite and vermin resistant and contain zero formaldehyde content and zero asbestos content.

All joints and frames between windows, in corners, on the ceiling etc. should be as smooth as possible, easy to access and clean to minimise dirt build-up. Window frames and other surfaces should be designed with an angle that will prevent build-up of dust.

Angled window-frame



smooth-surface joints

Angled surfaces

Washing and toilet facilities

The facility should have adequate and clean washing and toilet facilities which are kept away from the production areas.

Lighting

All production areas should have properly installed lighting which should provide sufficient light for the entire area. The lighting should resemble daylight conditions (at least 500 lux recommended). Staff require adequate lighting to improve visibility, thereby reducing the risk of contamination. The lighting should be

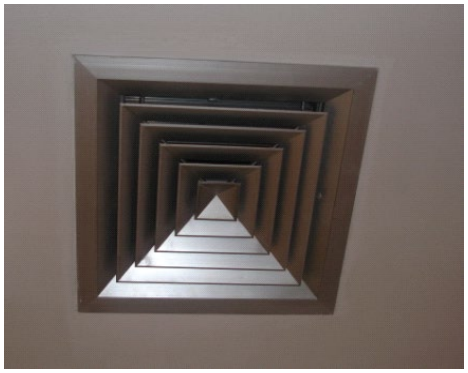
properly installed and should have brackets to stabilise them. It should be designed in such a way that it can be easily cleaned and maintained.

Ventilation

The infrastructure layout should have sufficient ventilation available or satisfactory alternative measures. Air should be appropriately filtered, particularly in the filling and processing zones. The non-powdered and dry production areas should have either "One Pass Filtration Efficiency" or "Clean Air Delivery Rate". These air purifying systems will monitor the percentage rate of pollution emitted into the environment. The dry or powdered product cosmetics require a dust collection system to be installed.

Types of ventilation

Centralised air-condition



Centralised air-condition

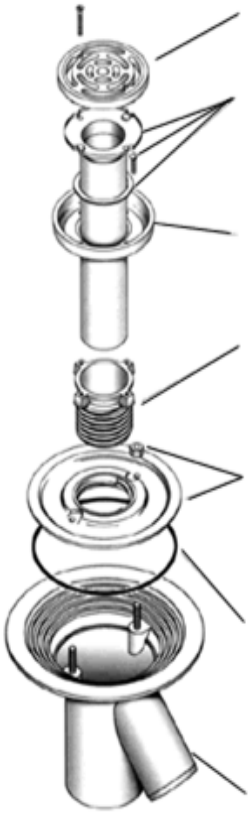
Ventilation fan and filter

Wall air-conditioning

Pipework, drains and ducts

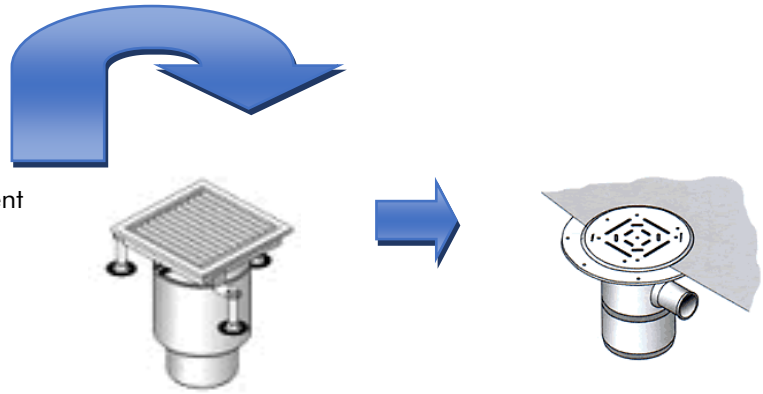
Ducts and pipework should be installed without risk of condensate dripping on materials and equipment. Faulty and leaky pipes are hazardous and could cause direct or indirect contamination of the product. Any exposed beams, pipes or ducts should be supported by brackets that are securely mounted and easy to maintain and clean. Drains should be kept clean and allow no back flow.

Drain design



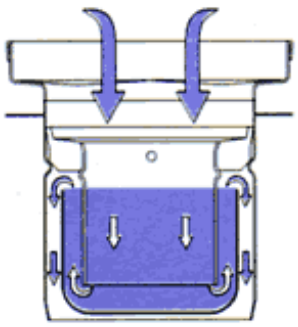
Equipped to prevent back flow

Open channels avoided



Cleaning and sanitation

The GMP standard requires that all cosmetic manufacturing premises be maintained and in a clean condition. Cleaning and sanitation procedures should be conducted to protect each product. The cleaning agents should be specified and effective. What's more, there should be defined programmes according to the needs of each area.



The drain-catch

prevents foul air passing through the drain from stagnant or filthy water within the connection pipe work.

Maintenance

Building maintenance is the totality of all actions which keeps a building functioning effectively.
The premises should be kept in a good state of repair. The maintenance programme is an important part of this chapter, as it ensures that the premises will be kept in a condition compliant with the GMP standard. The Building Maintenance Manual and Building User's Manual will provide all additional information required, as well as templates to assist in record keeping.

Consumables

As a general rule, food, drinks and medicines should not be brought into the cosmetic manufacturing areas. It is important that consumables to be used do not affect the products. Contamination of any kind could affect the quality of the product and could lead to rashes or illnesses. The staff should be briefed on this rule during training.

Pest control

It is the responsibility of the Quality Control officer that regular pest control systems are adhered to. The programme should cover both the exterior and interior premises.

Chapter 4 Premises: Checklist

Guidance for Compliance: Chapter 4 - Premises							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	4.	**Premises/Production Plan**					
	4.1	**Principle**					
48	4.1.1a	Are the premises designed, constructed and utilised so as to ensure protection of the product?					
49	4.1.1b	Is efficient cleaning, if necessary, sanitising and maintenance of the premises possible?					
50	4.1.1c	Are the premises designed, constructed and utilised so as to minimise the risk of confusion when moving products, raw materials and packaging materials?					
51	4.1.2	Have areas of different hygienic requirements been defined, identified and have measures been assigned to the areas?					
	4.2	**Types of Area**					
52	4.2	Have separate or defined areas been provided for storage, production, quality control, ancillary, washing and toilets?					
	4.3	**Space**					
53	4.3	Is sufficient space provided?					
	4.4	**Flow**					
54*	4.4	Has the flow of personnel, materials and products been defined and is it complied with?					
	4.5	**Floors, Walls, Ceilings, Windows**					
55	4.5.1a	Are floors / walls / ceilings / windows kept clean and in good repair?					
56	4.5.1b	Are floors / walls / ceilings / windows designed in such a way that thorough cleaning is possible?					
57	4.5.1c	Have floors / walls / ceilings / windows been designed in such a way that sanitisation is possible?					
58	4.5.2	Are there windows which are opened to the outside environment or to other production / storage areas)?					
		Are these windows designed in such a way that an adverse effect on cosmetics is not possible (e.g. by inserting a screen …)?					
59	4.5.3a	Has the design of the production area considered a crack-free and smooth floor condition (depending on the product type)?					
60	4.5.3b	Has the design of the production area considered for proper cleaning and sanitisation (depending on product type)?					

Guidance for Compliance: Chapter 4 - Premises							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
61	4.5.3c	Has the design of the production area, considered the resistance of floors and walls to corrosive cleaning and sanitising agents (depending on product type)					
	4.6	**Washing and Toilet Facilities**					
62	4.6	Are sufficient toilet and washing facilities available which are exclusively intended for employees of areas with relevance for hygiene and can these be accessed directly from the corresponding areas?					
	4.7	**Lighting**					
63	4.7.1	Is lighting adequate?					
64	4.7.2	Is lighting protected from potential breakage?					
	4.8	**Ventilation**					
65	4.8	Is ventilation sufficient and is it ensured that there is no adverse influencing of the cosmetic product (eg screen, ventilation with filter stages, no direct flow of air onto products…)?					
	4.9	**Pipework, Drains and Ducts**					
66	4.9.1a	Is pipework designed in such a way that, in the event of a leakage, there is no contamination of equipment, materials, cosmetic products etc?					
67	4.9.1b	Is pipework designed in such a way that condensation does not contaminate equipment, materials, cosmetic products, etc?					
68	4.9.1c	Is pipework designed in such a way that there is no contamination of equipment, materials, cosmetic products etc. because of drip of soil?					
69	4.9.2a	Are drains designed in such a way that they are always clean?					
70	4.9.2b	Are drains designed in such a way that a backflow of wastewater is excluded?					
71	4.9.3a	Are overhead roof beams, pipes and ducts exposed? How is this corrected?					
72	4.9.3b	Are exposed pipes installed at a sufficient distance from the wall / ceiling to allow thorough cleaning?					
73	4.9.3c	Are there any technical alternatives concerning pipework, drains and ducts to protect products?					
	4.10	**Cleaning and Sanitisation**					
74	4.10.1	Is the production area and in particular the areas which require a high degree for hygiene in a clean condition?					
75	4.10.2	Is cleaning / sanitisation carried out for the protection of the product?					

Guidance for Compliance: Chapter 4 - Premises							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
76	4.10.3a	Are the cleaning agents used defined?					
77	4.10.3b	Are the defined cleaning agents effective?					
78	4.10.3c	Are the sanitisation agents used defined?					
79	4.10.3d	Are the defined sanitisation products effective?					
80	4.10.4a	Are cleaning / sanitisation measures adjusted to the respective needs and carried out with appropriate, effective and defined agents?					
81*	4.10.4b	Are cleaning / sanitisation measures adjusted to the respective needs and are these termed effective? and documented?					
	4.11	**Maintenance**					
82*	4.11	Is a corresponding maintenance plan for buildings, premises etc, available? Are the measures documented?					
	4.12	**Consumables**					
83	4.12	Is it ensured that consumables (lubricants, cleaning wipes, auxiliaries…) do not have an adverse effect on the cosmetic products?					
	4.13	**Pest Control**					
84	4.13.1	Are the production premises designed in such a way that access by insects, rodents, pests and other vermin is virtually impossible?					
85*	4.13.2	Is there a programme for pest control and is it documented?					
86	4.13.3	Are there any preventive measures taken to ensure that the outdoor area is prevented from harbouring pests (e.g. any trees very close to the buildings / no adequate space between building and waste containers, etc)?					

References: IKW Cosmetics GMP based on ISO 22716

Reference Websites:

A WHO guide to good manufacturing practice (GMP) requirements:
https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 22 August 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/
Last viewed 22 August 2021

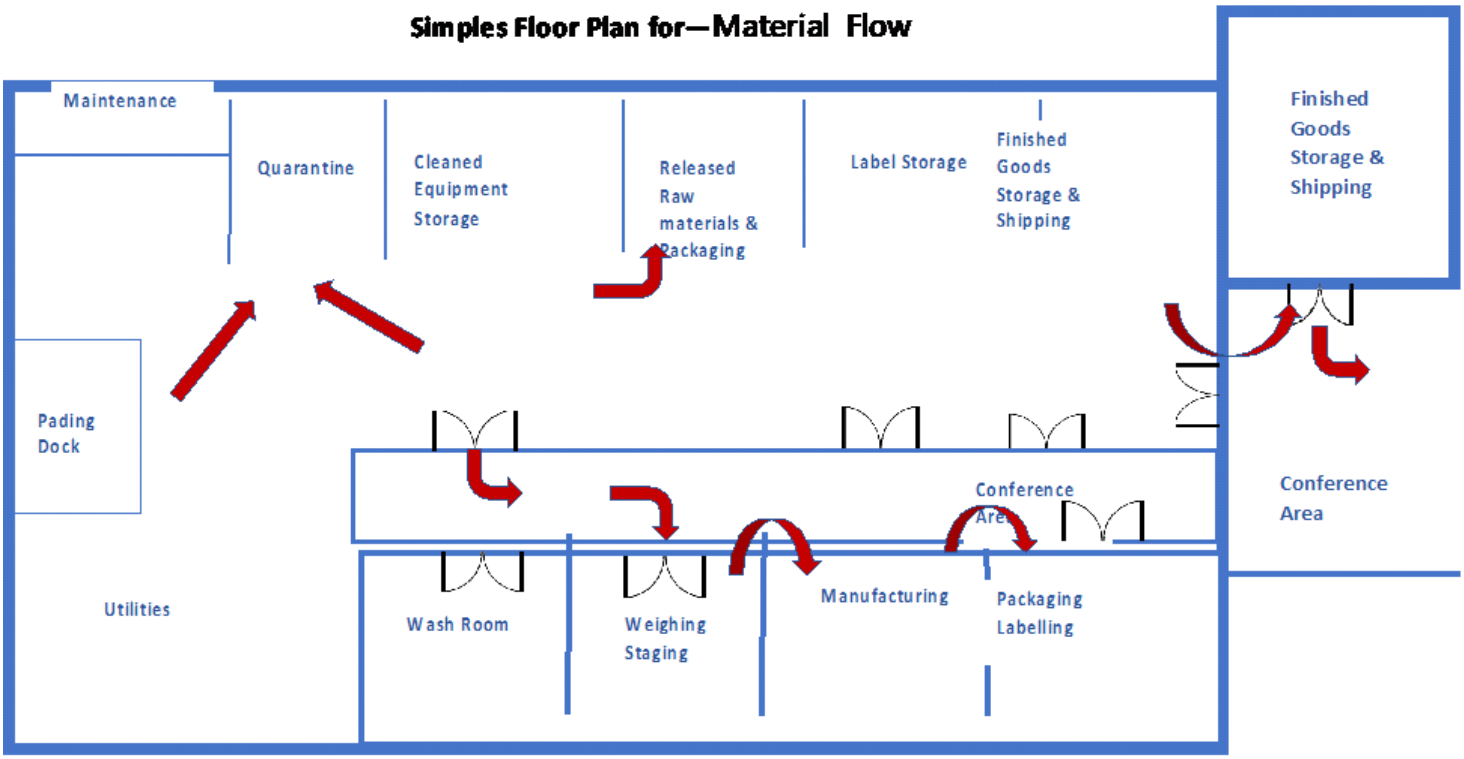
WHO Technical Report Supplement 5:
https://www.who.int/medicines/areas/quality_safety/quality_assurance/supplement_5.pdf?ua=1
https://www.bsria.com/doc/JDdLND/
Last viewed 22 August 2021

Sanitations Programme: https://www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/basic-gmp-program/pubs/w97i_sanitation_pgm.doc
Last viewed 24 August 2021

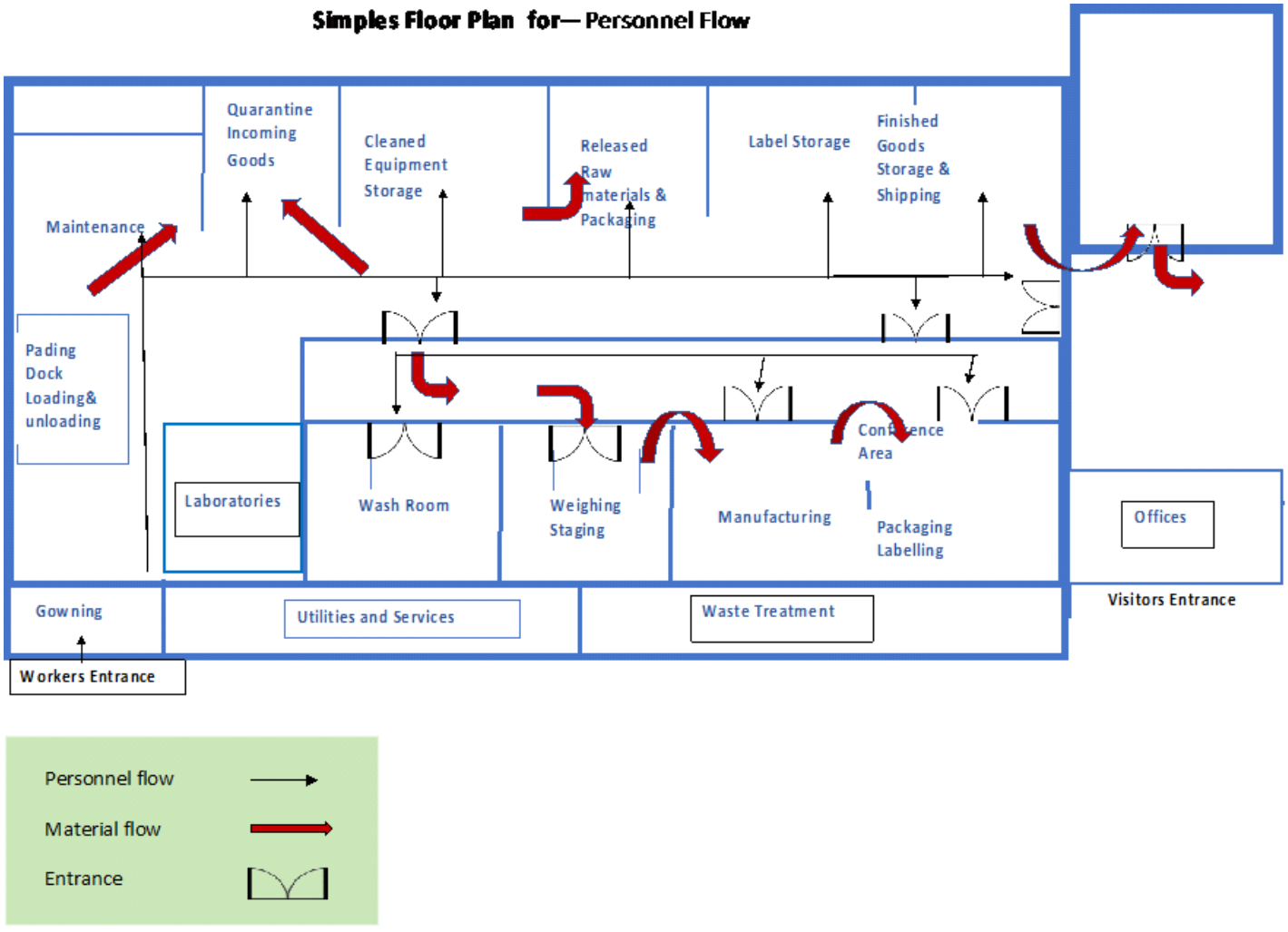
Pest Control – ASEAN: https://asean.org/wp-content/uploads/2012/10/ASEAN-TMHS-GMP-Training-Chapter-4-Annex-7-Sample-SOP-on-Pest-Control.pdf
Last viewed 29 September 2021

Slideshare - Small scale manufacturing facility: https://www.slideshare.net/InstantGMP/gmp-dietary-supplement-manufacturingfinal
Last viewed 29 September 2021

4.4.54. Annex1: Floor plan: Flow of material in production



4.4.54. Annex 2: Floor plan – Flow of personnel in production plant



4.10. SOP 81 - Cleaning and sanitation programme

Logo	**Standard format for SOP:** Cleaning and Sanitation Programme Department: _____ Policy No: _____

Company header: _____

Policy: _____

Cleaning and Sanitation Programme

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Purpose:

WHY: [Why is this procedure written.] [Why is it being performed.]

The aim of sanitation measures is to eliminate all potential sources of cross-contamination from areas where product quality is at risk and minimise control microbial activity.

Scope:

Sanitation should be carried out in order to prevent cross-contamination and contamination of personnel during the cosmetic manufacturing processes.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

The scope should cover all aspects of manufacturing of cosmetic products:

- Personnel
- Premises
- Equipment and apparatus
- Production material and containers
- Products for cleaning and sanitising
- All potential sources of contamination

Responsibility:

WHO: [Who performs the procedure, who is responsible to see it is performed correctly.]

Sanitation and pre-operational activities must be monitored [Specify frequency], by [Specify name/title, ex: supervisor, manager)]. The information must be recorded on the sanitation record [Specify, using the Sanitation Record template].

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.

There are two classes of cleaning compounds:

- acid cleaners, and
- alkaline cleaners

Chemical formulations for acid and alkaline compounds may vary according to the following:

- chemical dispensing method
- method of cleaning
- type of processing equipment to be cleaned

Acid cleaners

Acid cleaners are used to remove mineral deposits, such as descaling washing machines, steam tables and removing rust from rest rooms or rust on shelving. Examples include products with phosphoric acid, nitric acid etc. This is a strong acid mainly used for heavy duty cleaning. The products vary depending on the specific purpose of the product.

Method for acid cleaners: when using these products always wear gloves;

- Read dilution instruction carefully, water should not be added to acid, but acid should be added to water
- Pre-rinse with water
- Alkaline wash,
- Acid wash
- Sanitise (remove impurities)

Alkaline cleaners

Alkaline cleaners such as chlorine bleach, trisodium phosphate and sodium carbonate, or washing soda are used to clean fatty and oily surfaces.

Method for Alkaline Cleaners:

- Read application instruction on the product carefully. Alkaline cleaners can be used in hot water or as a spray.
- Pre- rinse surface with water
- Alkaline wash
- Sanitise

Procedure: A general, wet cleaning and sanitising procedure has six basic steps. **[Specify particulars for your facility]**

- Cleaning operations shall be performed in a manner to prevent contamination of materials and products.
- Only cleaning compounds and sanitisers authorised shall be used for cleaning.
- All cleaning compounds and sanitisers shall be properly labelled and stored in a locked compartment, away from production and food storage areas.
- Cleaning equipment and tools shall be supplied and be readily available for use.

- Equipment and utensils should be kept clean.
- The written instruction for cleaning and sanitation for each piece of equipment and each utensil should be provided. Manuals from equipment manufacturers may have supplied these upon delivery. Please consult these manuals for reference.

How: [Clear concise step by step instructions on how to perform the procedure. This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included if necessary.]

This should include:

- Preliminary steps that must be done before beginning the actual procedure.
- Safety considerations: [Precautions for work with physical, chemical, or biological hazards (containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.)].

Health and Safety Information:

- Any equipment with sensitive electrical panels must be wrapped with plastic to prevent moisture damage.
- Follow equipment lock-out/tag-out procedures where necessary. **[Specify your procedure]**
- Chemical supplier(s) must provide current Material Safety Data Sheets (MSDSs) for all chemicals. Keep them readily accessible in **[Specify location, ex: blue binder main office]**.
- All employees must wear appropriate personal protective equipment (PPE), ex: gloves, goggles/face masks, etc.
- **Use chronological instructions. It is useful to number the steps so that repeat steps can be referred to rather than making the SOP very long.**

Simple Basic Sanitation Procedures:

- Remove gross build-up and discard in waste container. Do a rough cleaning procedure, *[Specify how you will do it, ex: with a brush]*.
- Pre-rinse the surface/area, using warm, clean water at low pressure. When using hoses, minimise spray by controlling the pressure and direction. This helps prevent cross-contamination. **[Specify details on your pre-rinsing method]**
- Clean the surface/area, using **[Specify name of the chemical product, ex: ZZZ Detergent]**. Ensure all surfaces are cleaned, especially any crevices or cracks. If required, clean manually using brushes or other tools to remove soil from surfaces **[Specify how, ex: using a scrub].** Allow the cleaner to sit for **[Specify manufactures' instructions]**.
- Rinse off all the cleaner, using warm, clean water.
- Inspect the equipment to ensure there is no visible debris or greasy film. Re-clean if needed.
- Sanitise using **[Specify name of the chemical product, ex: YYY Sanitiser]**. Ensure all surfaces are sanitised, including the underside. Follow rinsing procedure for the sanitiser if required. **[Specify manufacturer's instructions]**

Equipment parts and utensils should be washed in a separate area. [Specify instructions and location. Ex: in a designated washing area by following poster instructions]

After Sanitation/Before Production Starts (Pre-operational Assessment)

- Equipment and parts must be inspected again for cleanliness and damage and then reassembled using the instructions in the corresponding sanitation standard operating procedures (SSOP).
- Sanitation and inspection completion must be recorded on the Sanitation Record. **[Specify process/recording using the Sanitation Record template]**

General Housekeeping Procedures:

- Trash and waste materials include *[Specify what is trash and waste and how each material is to be handled, ex: plant waste goes in sealed plastic bags, paper goes in recycle bins]*
- Waste containers must be emptied and cleaned daily by **[Specify person/title responsible].**

- Keep containers well-maintained (no cracks or leaks) and clean.
- Ensure areas such as washrooms, locker rooms, lunchroom, office, are kept clean. **[Specify person/title responsible]**
- The exterior of the facility must be kept clean and tidy. **[Specify person/title responsible]**
- No equipment, pallets, etc., can be stored near the building.
- The grounds must be kept clean to minimise pests.
- The trash dumpster must be emptied **[Specify how often, ex: weekly]** by [Specify company name].
- Vehicles used to transport food products must be kept clean. Cross-contamination of ingredients, food products, packaging materials and chemicals used in sanitation or maintenance must be prevented during transportation. **[Specify how, ex: separating incompatible products or not transporting incompatible materials at the same time]**
- Storage areas of the facility must keep clean and tidy.

Specific Sanitation Standard Operating Procedures:

- A list of sanitation standard operating procedures (SSOPs) including detailed assembly and disassembly instructions for individual equipment and areas, includes:

  [*Specify all that apply to your facility and write down the specific procedures*]

  - Production room
  - Walls, ceilings, and floors
  - Equipment 1
  - Equipment 2…etc.

- Refer to the sheet containing the list of chemicals for a list of authorised chemicals for use in this facility. **[Complete a List of Chemicals template]**
- Refer to the Master Sanitation Schedule to determine cleaning frequency of equipment and structures other than those cleaned daily. **[Complete the Master Sanitation Schedule template]**
- There are 4 interrelated factors which affect the overall cleaning process.

When designing cleaning procedures these factors need to be carefully considered:

- Cleaning time
- Temperature
- Chemical being used
- Mechanical forces

Cleaning methods:

1. **Foam**: Foam is produced through the introduction of air into a detergent solution as it is sprayed onto the surface to be cleaned. Foam cleaning will increase the contact time of the chemical solutions, allowing for improved cleaning with less mechanical force and temperature.
2. **High Pressure**: High pressure cleaning is used to increase the mechanical force, aiding in soil removal. In high pressure cleaning, chemical detergents are often used along with increased temperature to make soil removal more effective.
3. **Clean in Place (CIP)**: CIP cleaning is utilised to clean interior surfaces of tanks and pipelines in equipment used for liquid processing. A chemical solution is circulated through a circuit of tanks and or lines then returned to a central reservoir, allowing for reuse of the chemical solution. Time, temperature and mechanical force are used to achieve maximum cleaning.
4. **Clean Out Of Place (COP)**: COP cleaning is used to clean removable parts of filters and parts of other equipment which require disassembly for proper cleaning. Parts removed for cleaning are placed in a circulation tank and cleaned using a heated chemical solution and agitation.
5. **Mechanical**: Mechanical cleaning normally involves the use of a brush either by hand or a machine such as a floor scrubber. Mechanical cleaning uses friction especially in food soil removal.

Reference Documents:

4.10.81. Annex 1: Form – Sanitation Record

4.10.81. Annex 2: Form – Cleaning Record

4.10.81. Annex 3: Form – List of cleaning chemicals

4.10.81. Annex 1: Form – Sanitation record

Logo	Cleaning Record Department: _____ Policy No: _____

Company header: _____

Policy: _____

Sanitation Record

Instructions

Pre-operational assessment: Confirm production area and equipment are visibly clean before allowing production to start. If not ready put an X and take corrective action. Then check again.

Post operational assessment: Sanitation activities and completion of this record sheet must be done by [Specify name/title of trained employee]. When cleaning is complete, put a check in the box. If the equipment was not used, put n/a in the box. Initial and record all unmet requirements and corrective actions.

	Mon		Tue		Wed		Thu		Fri		Sat		Sun	
Concentration of Sanitiser														
Area 1	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
Equipment 1														
Equipment 2														
Equipment 3														
Area 2														
Equipment 1														
Equipment 2														
Initials:														

Deviations: _____

_____

Corrective Actions: _____

_____

4.10.81. Annex 2: Form – Cleaning record

Cleaning Record

Department:

Policy No:

Company header:

Policy:

All equipment that does not have to be cleaned daily **[Specify, ex: after each use]** must be included on the schedule to ensure that it is cleaned when needed or required.

M = monthly; **Q** = quarterly; **S** = semi-annually; **Y** = yearly

Year: _____ Instructions: initial and date the columns when the cleaning is completed.

Item	Freq	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Area 1													
Walls, ceilings	Y												
Fixtures	Y												
Drains	M												
Reefer	S												
Shelves	Q												
Equipment 1													
Equipment 2													
Area 2													
Walls, ceilings	Y												
Fixtures	Y												
Drains	M												
Shelves	Q												
Area 3													
Area 4													

4.10.81. Annex 3: Form – List of cleaning chemicals

List of Chemicals

Department:

Policy No:

Company header:

Policy:

Chemical	Supplier	Used for	Approval [Recommended]
(ZZZ Detergent)	*(Kleen Co.)*	*(Cleaning all equipment and utensils)*	*(Mar 10, 2021)*
(YYY Sanitiser)	*(Kleen Co.)*	*(Sanitising all equipment and utensils)*	*(June 6, 2021)*
(XXX Hand Soap)	*(Soap Co.)*	*(Washrooms, floor sinks)*	*(June 6, 2021)*

4.11. 82. Building maintenance plan (manual)

Building maintenance is the totality of all actions that keep a building functioning effectively

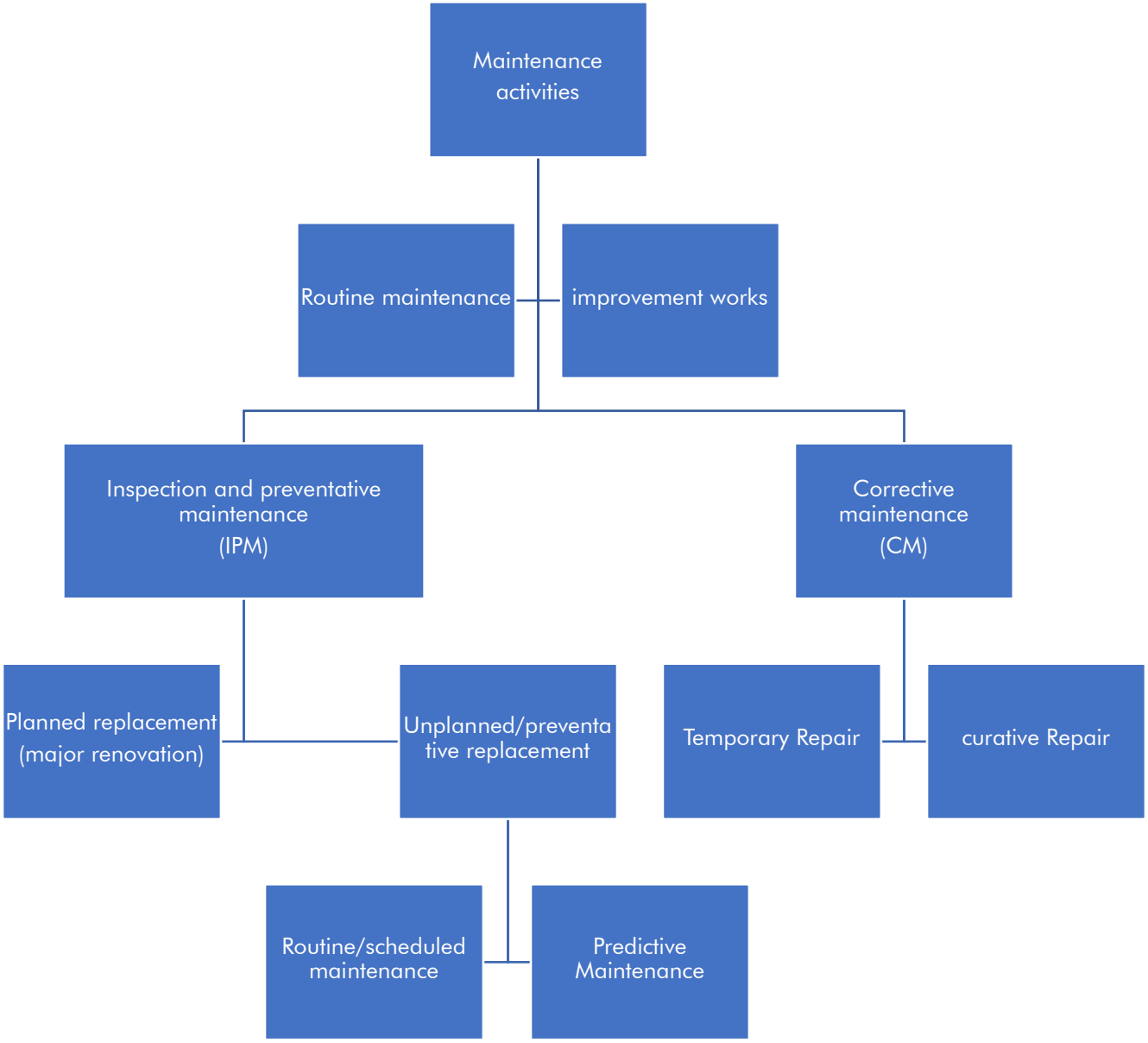
NB: This manual was constructed so that it may be printed and used as a leaflet, the entire document is a single supplement based on the GMP checklist requirement number 82.

4.11. 82. Annex 1: Table 1 - Coding system for a simple warehouse

G1- site preparation	
	G11-Ground contouring
	G12- Stabilisation
	G13- Foundations
G2- Fabric	
	G14-Floors
	G15- Stairs
	G16-Roofs
	G17-Walls
	G18- Frame/isolated structural members
G3-Fabric: parts of elements	
	G19- Carcass/structure/fabric
	G20-Openings
	G21-Internal finishing
	G22-Other parts of fabric elements
G4-Fittings/furniture/equipment (FFE)	
	G23-Circulation FFE
	G24-Rest, work FFE
	G25- FFE
	G26- Sanitary, Hygiene FFE
	G27- Cleaning, maintenance FFE
	G28-Storage, screening FFE
	G29-Works of art, soft furnishings
	G30-Special activity FFE
	G31-Other FFE
G5-Services: complete elements	
	G32-Water supply
	G33-Gas supply
	G34- Heating, ventilation and air-conditioning
	G35-Electric power
	G36-Lighting
	G37-Communications
	G38-Transport
	G39-Protection
	G40-Removal/disposal

G6-Services: parts of elements	G41-Other services elements G42-Energy generation/storage/conservation G43-Non-energy treatment/storage G44- Distribution G45-Terminals G46-Package units G47-Monitoring and Control G48- Other parts of services elements G49-Surface treatment G50-Enclosure/division G51-Special purpose works G52-Fitttings/furniture/equipment G53-Mains supply G54- External distributed services G55-Site/underground drainage

4.11. 82. Annex 2: Table 2 - Maintenance plan chart



Maintenance plan

A programmed IPM (Inspection and preventative maintenance) activity is necessary for the effectiveness of both financial and operational functions of a company. If an effective maintenance system is in place, CM (Corrective maintenance) would only comprise of a marginal section in light of the entire maintenance activity plan; although, there may always arise the occasional need for some unplanned "emergency" maintenance and adequate resources.

IPM (inspection and preventative maintenance) is subdivided into the following categories:

- Planned replacement: this safeguards that building components such as windows and floor finishes are changed when they are worn out, thereby reducing the necessity for emergency maintenance.
- Preventive maintenance: This safeguards that the building components are well-maintained and that they do achieve their assigned service life. This can be done through *routine scheduled maintenance* such as regular lubrication of mechanical parts, or through *predictive maintenance,* restoration of a minor issue that occurred during routine inspection, for example vibration in an air – conditioning unit, before it turns into a major issue and becomes an emergency.
- Corrective/emergency maintenance becomes necessary whenever the problem that arises is unexpected and requires immediate maintenance. Although the implementation of an effective IPM system will reduce these occurrences, they can never be entirely avoided.

CM (Corrective maintenance) is subdivided into the following categories:

- Corrective maintenance: is required in the event of any unexpected issue which must be handled immediately.
- Temporary repairs: a quick and short-term solution to the immediate problem, this will also delay further damages and loss. It is essential to schedule a permanent repair as soon as possible.

Curative repairs: Permanent immediate replacement or restoration. For example, if an air-conditioning unit unexpectedly fails, it may be replaced with a new unit.

Insert picture of your building in box	Address:	

Responsibility of:		**Position:**	
Building User Guide Issue Number:			
Date:			
This Building User Guide should be kept at all times in:			
Electronic version located at:			
Prepared by:			

Purpose of this manual

The Building User's Manual provides the end users/occupants of the building with a simple, quick and easy guide to the everyday functions of the building in order to ensure a safe and healthy work environment while complementing the efficient operation of the building to the full potential provided by the design.

It is intended that the Building Manual will focus on information that is relevant to the building and its operation; while the Building Maintenance Manual will focus on information relating to the management of people and how they interact with the building. For example, information on how to shut down the main gas supply in the event of a gas leak should be included in the Building User's Manual and information on the occupants' fire evacuation procedures included in the Building Maintenance Manual.

With the gap that often exists between the design concept and the operators' understanding of how the building works, the Building User's Manual and Building Maintenance Manual offer the opportunity to close this gap, and in doing so, reduce excessive energy use and increased maintenance costs.

4.11. 82. Annex 3: Form - Building user's manual updates and reviews

This user manual should be reviewed six monthly/annually (delete as necessary) and updated when changes to structure, layout, fabric or services of the building have been made. Any changes to the document including removal or adding of pages should be recorded.

Review date	Description and updates/changes	Pages updated or removed	Facilities manager signature

4.11. 82. Annex 4: Floor plan - Building services information

General building information

Provide a general description of the building, location, design features, services and local infrastructure/amenities available. Provide a "Pre-arrival pack" or list of information to be passed on to planned visitors/contractors/new staff telephonically, electronically or by post as appropriate, when booking an appointment. Also provide details of any shared facilities including who has access to these, when, why and how. For example in a building where tenants have independent sections served by independent services, but have shared access via lifts and stairwells, or a business park with shared security access to communal visitor parking and dedicated tenant parking.

Building description	
Insert your picture here	Insert your picture here

Location map

General Floor Plan - First floor

Site Master Plan

Visitor information

Building shared facilities

4.11. 82. Annex 5: Form - Building environment

Include details on heating, cooling, ventilation, lighting and acoustics. Also include a brief description of distribution/attenuation method(s) and positioning of units (walls, floor or ceiling). Provide a floor plan showing main control point location and state the maximum and minimum set points, operational times, override/alternate settings. Also provide a brief description on who should adjust the temperatures on the main controls and how to and when to adjust the temperatures on main controls, and details of zone and or local user control settings such as TRVs (Thermostatic Radiator Valves) on radiators, and detail optimum settings for efficient operation.

Element description	Distribution/attenuation method	Photos

Temperature control		Photos
Time schedule		
Temperature setpoints		
Out-of-hours operation		

4.11. 82. Annex 6: Form – Security system

Include details on the type of security system, times for manual and automatic activation, and which personnel are authorised to activate or deactivate the system. Provide details of the entry and exit procedure during normal hours and outside of normal working hours and provide a list of personnel who are authorised to activate or deactivate the system. Include a list of times for manual and automatic activation. Provide details of entry/exit procedure during normal hours and outside normal working hours.

Security system description	
Links to external organisation	

Name and contact details of authorised personnel	**Telephone**

Normal operating	**Times**
Alarms off	
Alarms on	
Alarms on (out-of-office hours)	

Entry procedure during normal working hours	**Photos**

Exit procedure during normal working hours	Photos

Entry procedure outside normal working hours	Photos

Exit procedure outside normal working hours	Photos

4.11. 82. Annex 7: Form – Emergency information

Provide reference to master Health and Safety documents.

Health and Safety documents

4.11. 82. Annex 8: Form – Fire response and alarm system

Type of alarm system

4.11. 82. Annex 9: Form – Fire evacuation procedures

Include details on the procedure for calling the fire brigade, show locations of the fire escape routes and exit doors and assembly points outside the building in respective drawings.

Fire emergency procedure

Use of fire equipment

4.11. 82. Annex 10: Form – First aid

Provide a link to the list of registered first-aid personnel in the building with contact numbers and areas of responsibility. Include the level of first aid training (use of defibrillator if applicable). Also give the procedure on calling for assistance, for example, in an emergency – person collapsed, chest pain, difficulty breathing, or serious injury, or with an incident – person feeling unwell, a minor trip, fall or injury. Also provide a floor plan showing the location of first aid facilities or equipment.

Calling for assistance

Emergency first-aid procedure	**Photo**

Minor injury/illness first-aid procedure

4.11. 82. Annex 11: Form – Building utility and environmental information

Provide an overview of the company policies and practices relating to company culture, desk-top policies, telephone equipment and protocol, media, email and internet protocols, dress code. If a canteen is provided, include eating and drinking protocols.

Company policies and protocols

4.11. 82. Annex 12: Form - Mechanical

Provide information for manual and automated blinds and how these can be adjusted. This includes ventilation strategies in natural/mechanical/mixed mode. List actions that can affect the efficiency of the systems and the energy conservation in the building such as, blocking supply outlets with filing cabinets or storage boxes, use of natural ventilation when the system is in automated mode, the opening of windows and doors – when to and when not to, the use of blinds in winter time, affecting the natural lighting, and lack of use of blinds in summer time, causing additional solar heat gain. Give high flow temperature set points for each season.

Blind adjustment

Set point for winter temperatures	Set point for summertime temperatures

4.11. 82. Annex 13: Form - Ventilation

Provide a system that will favour efficiency and adequacy based on the structure of the building. A ventilation strategy or specific alternative measures are needed to ensure the regulation of environmental conditions inside the production area is conducive to the safety requirements of the product. The ventilation system should be constructed in a manner that will result in reduced risks of product contamination from dust exposure.

Ventilation strategy

4.11. 82. Annex 14: Form - Electrical

Provide information on lighting and small power strategy, provision of UPS if applicable, provision of emergency lighting. List actions that can affect the efficiency of the systems and the energy conservation in the building such as: desk electric heaters/desk electric fans, use of override/local controls in areas with automated lighting systems and the use of lighting control procedures in lightly used areas. Provide Switch-off policy what, where and when.

Lighting and small power strategy	**Photos**

Uninterruptible power supply (UPS)

Emergency lighting

List actions that affect energy efficiency and conservation

Switch-off policy

4.11. 82. Annex 15: Form - Communications

Provide information on the telephone system and operational procedures needed. You should also provide information on the computer system used and include whether connectivity by ehernet, or wireless and whether access is via intranet, extranet, internet.

Communication procedures and policies

Connectivity	
Ethernet	**Wireless**

Company network options

4.11. 82. Annex 16: Form - Water management

Water strategy

Provide information on the water supply and management strategy, water metering, sub-metering and monitoring and water saving/recycling features such as recycled grey water and rainwater harvesting. Provide a description of internal and external landscaped areas, irrigation system/hand watering/type of plants and reliance on natural precipitation only.

Water supply and management strategy

Water metering	**Sub-metering**	**Monitoring**

Water saving features	**Photos**

Internal landscape areas	**Photos**

External landscape areas	**Photos**

Water leaks	**Photos**

4.11. 82. Annex 17: Form - Domestic water

Provide information on the areas where potable water is supplied, the location of water coolers, bottled water and hot water supplies. List water saving features such as aerating taps, timed shut off, proximity sensors, flow rate restriction on showers, dual/low flush toilets, waterless urinals, occupation sensors and solenoid shut off/isolation valves.

Quality of the water, which is used as raw material in production can be a high risk for microbiologically unstable products and as a result will require regular testing. This is further elaborated on in Chapter 6 of Raw Materials and Packaging Materials.

Potable water locations

Water cooler/bottled water locations	**Photos**

Hot water supplies	**Photos**

Water saving features

4.11. 82. Annex 18: Form - Materials and waste management materials purchasing policy

Include information such as a responsible source for materials and the use of recycled materials.

Materials Purchasing Policy

4.11. 82. Annex 19: Form - Waste management policy

Include information about the recycling facilities used in the building, such as the use of bins, shredders, and compactors. Also include information on the use of recycling strands, such as paper, cardboard, plastic, cans, glass and batteries. Show locations of the recycling collection points on floor plan in section 1.1, and provide a timetable for collections and contact details for special arrangements.

Recycling facilities

Recycling strands

Contact details

4.11. 82. Annex 20: Form - Transport facilities

Transport

Include information on public transport, show bus stops, train stations and taxi ranks on location map and provide links to websites showing timetables, ticket prices and alternative transport, provide details of carpool/car share schemes and provide details of 'Ride to Work' schemes.

Public transport

Alternative transport

4.11. 82. Annex 21: Form - Parking

Show the location of the building, location of offsite parking and other details on location map. Show dedicated visitor parking, dedicated/preferential car share parking, general staff parking, location of bicycle racks and location of access to site for pedestrians and cyclists, and all pedestrian and cycle routes on site on the general site plan. (This is not strictly a GMP requirement but may prove constructive to the efficiency of the building management system).

Parking and cycle racks

4.11. 82. Annex 22: Form – Refit and rearrangement considerations

Re-fit building/building sections

Provide information on the following considerations, design load/occupation densities, design levels/limitations of existing building services, scope for extending/upgrading existing building services, and provision for additional building services. Include the application of the material and waste management policies see (4.11. 82.Annex 19).

Design load/occupational densities

Design levels/limitations of existing building services

Additional building services

Material and waste management policies

4.11. 82. Annex 23: Form – Re-arrangement/addition of furniture

Provide information about the impact on all aspects of the building environment (heating, cooling, ventilation, lighting and acoustics) due to moving furniture/partitions from designed layout, adding furniture/partitions/shelving and changing occupation densities.

Also consider temporary/permanent placement of loose furnishings such as spare chair, coat rack, filing cabinet and storage boxes. List the impact this has on all aspects of the building environment (heating; cooling; ventilation; lighting and acoustics) through blocking or restricting access to supply grills, extract vents, control points, sensors, service and maintenance hatches and emergency routes or services. Show layout of furniture fittings on the floor plans.

Furniture and fittings

Temporary/permanent furnishings

4.11. 82. Annex 24: Form – Reporting provision

Reporting procedures

Include details on the protocol for reporting conditioning requirements such as temperature setting and ventilation. General maintenance requirements such as a faulty light fitting, leaking tap, window not opening and blinds not working should also be provided. List operational maintenance requirements i.e. no power supply, no telephone/internet connection and toilet not flushing and report any emergency requirements such as burst pipes and electrical short or sparking.

Conditional requirements
General maintenance requirements

4.11. 82. Annex 25: Form – Responsible parties

Include contact information for the following, help desk, health and safety manager, facilities manager and maintenance team.

Operational maintenance requirements

Emergency requirements

Department	Contact information	
Facilities Manager	Name:	
	Telephone:	
	Email:	
Facilities Maintenance Manager	Name:	
	Telephone:	
	Email:	
Administration Manager	Name:	
	Telephone:	
	Email:	
Health and Safety Officer	Name:	
	Telephone:	
	Email:	
Reception (Help Desk)	Name:	
	Telephone:	
	Email:	

4.11. 82. Annex 26: Form – Training

Compulsory training

This should include training details on the following information: site introduction for new employees (building users/occupants), visitors and contractors. Provide specialist training for selected personnel in air conditioning and heating, lighting and control, water waste management and recyclable procedures. Also include training for emergency procedures, including general aspects covered in site induction, with specialist training for selected personnel such as fire, first aid and lift failures.

Site induction	
Visitors	
New staff	

Specialist training for building services

Emergency procedures

Additional training

This should include training details on any innovative/energy saving methods or equipment and training for general internal/external projects aimed at meeting areas of corporate social responsibility.

Additional training

4.11. 82. Annex 27: form - Maintenance records

Inspection checklist: Typical Office			
Location:	*(South warehouse)*		
Area:	*(Typical Office)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis.*)	Reason: *(routine inspection or faulty functioning)*	Action required:	Action taken:
	Reason: *(routine inspection or faulty functioning)*		

Inspection checklist: Dry production			
Location:	*(South warehouse)*		
Area:	*(Dry production)*		
Element:	G**- **		
Check for: *(list item you are checking in a case-by-case basis.)*	Reason: *(routine inspection or faulty functioning)*	Action required:	Action taken:
	Reason: *(routine inspection or faulty functioning)*		

Inspection checklist: Wet Production			
Location:	*(South warehouse)*		
Area:	*(Wet Production)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis.*)	Reason: (*routine inspection or faulty functioning*)	Action required:	Action taken:
	Reason: (*routine inspection or faulty functioning*)		

Inspection checklist: Typical Warehouse			
Location:	*(South warehouse)*		
Area:	*(Typical Warehouse)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis*.)	Reason: (*routine inspection or faulty functioning*)	Action required:	Action taken:
	Reason: (*routine inspection or faulty functioning*)		

Inspection checklist: Storage – Incoming Materials			
Location:	*(South warehouse)*		
Area:	*(Storage – Incoming Material)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis*.)	Reason: (*routine inspection or faulty functioning*)	Action required:	Action taken:
	Reason: (*routine inspection or faulty functioning*)		

Inspection checklist: Storage – Finished Goods			
Location:	*(South warehouse)*		
Area:	*(Typical Office)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis*.)	Reason: (*routine inspection or faulty functioning*)	Action required:	Action taken:
	Reason: (*routine inspection or faulty functioning*)		

Inspection checklist: Storage – Dispatch Cosmetic Ingredients			
Location:	*(South warehouse)*		
Area:	*(Storage – Dispatch Cosmetic Ingredients)*		
Element:	G**- **		
Check for: (*list item you are checking in a case-by-case basis*.)	Reason: (*routine inspection or faulty functioning*)	Action required:	Action taken:
	Reason: (*routine inspection or faulty functioning*)		

4.11. 82. Annex 28: form - Replacement, and maintenance task record

Element inspection, replacement and maintenance task record for a typical office		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	
Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*Maintenance manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	Check box
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
	Use fall arrest harness with access by fixed ladder at north end	
Preventive maintenance actions:	Wash off organic build-up	
	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	

Element inspection, replacement and maintenance task record of a warehouse		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	

Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*O and M manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	Check box
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
Safe access requirements: Preventive maintenance actions:	Use fall arrest harness with access by fixed ladder at north end	
	Wash off organic build-up	
Preventive maintenance actions: Inspection tasks:	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	
	Check for leaks	

Element inspection, replacement and maintenance task record for incoming materials		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	
Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*Maintenance manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	Check box
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
	Use fall arrest harness with access by fixed ladder at north end	
Preventive maintenance actions:	Wash off organic build-up	
	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	

Element inspection, replacement and maintenance task record for finished goods		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	
Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*Maintenance manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	**Check box**
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
	Use fall arrest harness with access by fixed ladder at north end	
Preventive maintenance actions:	Wash off organic build-up	
	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	

Element inspection, replacement and maintenance task record for cosmetic Ingredients		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	
Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*Maintenance manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	Check box
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
	Use fall arrest harness with access by fixed ladder at north end	
Preventive maintenance actions:	Wash off organic build-up	
	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	

Element inspection, replacement and maintenance task record for dry production		
Location:	*South Warehouse*	
Area:	*Typical Office*	
Element:	*(e.g. G24 – Roof)*	
Sub-element:	*G24.1 – External cladding*	
Description:		
Relevant drawings:		
Technical information:	*Maintenance manual section G24.1*	
Replacement interval and rationale:	*25 years (25-year thermal performance warranty, 30-year coating warranty)*	
Inspection schedule:	*Annually, starting __/__/___*	**Check box**
Inspection tasks:	Check for leaks	
	Check for build-up of dirt and organic matter which can trap water and cause corrosion	
	Check for damage and corrosion to external and internal surfaces, especially at cut edges, taps and overhangs	
	Check fixings and fixing caps	
	Check sealant tape at laps	
Safe access requirements:	Mobile access platform for internal lining inspection	
	Use fall arrest harness with access by fixed ladder at north end	
Preventive maintenance actions:	Wash off organic build-up	
	Prepare and recoat damaged or corroded areas using repair kit	
	Replace loose or damaged areas through fixings and replace missing caps	
	Replace damaged or displaced joint sealant tape	

4.11. 82. Annex 29: Form - Report sign-off and summary sheet

Date	Change summary	Reason for change:	Approved By:	Signature:

4.13. SOP 85 -Pest control programme

Logo	**Standard format for SOP:** Pest control Department: _____ Policy No: _____

Company header: _____

Policy: _____

Pest Control Programme

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Scope:

This standard health procedure applies to the cosmetic manufacturing area and the surrounding of [company name]

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

WHO: [company name] Pest control qualified Technician

[company name] QA (quality assurance) Technician

Who performs the procedure, who is responsible to see it is performed correctly?

Responsibility:

WHO: [Who performs the procedure, who is responsible to see it is performed correctly?]

Sanitation and pre-operational activities must be monitored [Specify frequency], by [Specify name/title, ex: supervisor, manager)]. The information must be recorded on the sanitation record [Specify, using the Sanitation Record template].

Material and equipment:

WHAT: [What is needed to perform the test. The list should be complete and specific.]

Procedure:

How: Clear, concise step-by-step instructions on how to perform the procedure. This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included, if necessary.

It should include:

- Preliminary steps that must be done before beginning the actual procedure.
- *Conduct a WEEKLY inspection of both inside and outside of the premises for signs of pests and record in the Pest Control Inspection Record Form.*
- *All pest control devices utilised on the premises should be labelled with a serial number that is clear and legible.*
- *All pest control traps or baits must be checked, dated and signed off by the qualified pest control technician and QA technician.*
- *Any pests found in the traps or baits must be recorded in the Pest Control Monitoring Record.*
- *Locations of all traps or baits must be marked for easy identification of the traps' location for all personnel or staff.*
- Safety considerations: Precautions for work with physical, chemical, or biological hazards (containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
- The chronological instructions. It is useful to number the steps so that repeat steps can be referred to rather than making the SOP very long.

1. Interior facility:
   1.1. The use of poisonous baits inside the facility is strictly forbidden.
   1.2. Any rodent infestation can be controlled with mechanical traps positioned at 5 – 10-meter intervals along the interior perimeter of the building, especially the entrance leading to the outside of the building.
   1.3. Inspect traps weekly. There are (number) traps on the premises.
   1.4. Rodents must be disposed of directly into the outside garbage can only. Traps must be scraped and cleaned at regular intervals.
   1.5. Each trap must be tested and inspected to make sure they are functioning properly.
2. Fly and insect control:
   2.1. Insects are controlled by electric insect eradicators (EIE).
   2.2. All EIE may not be installed within three meters of cosmetics manufacturing, packaging or storage areas.
   2.3. Catch trays must be emptied weekly and sticky pads monitored and replaced when required.
   2.4. Lights should be kept on 24 hours a day.
3. Exterior and perimeter of the facility
   3.1. Bird Control:
      - Inspect the area for any bird activities. There should be no birds in the proximity to any raw materials, in-process material, packaging and storage process areas.
      - Windows should always be closed or meshes should be installed to all external air outlets and inlets to prevent any bird entry.
4. Rodent Control:
   4.1. All exterior bait stations contain poison and must be securely fastened to prevent displacement from wind etc.
   4.2. Bait stations are to be positioned tightly against the wall with opening parallel and closest to the wall.
   4.3. Bait stations are to be inspected every alternative week. There are [number] bait stations in the [company name]
   4.4. Dispose of old empty packages in a small garbage bag directly after inspection then toss it into the outside garbage immediately.
5. Monitoring:
   5.1. Pest Control Qualified Technician and QA Technician shall check date and sign off on labels inside all traps to be placed around the facility.
   5.2. Pest Control Qualified Technician inspects traps, baits and electric insect eradicators every week.
   5.3. QA Technician checks interior traps, baits and electric insect eradicators every other week.

6. Reporting:

WHAT NEXT:

- Indicate where the results should be recorded.
- Explain what to do if there are problems during the test.

7. Corrective action:

7.1. If the existing pest control programme is ineffective, then QA manager shall change the programme.

7.2. The Pest Control Technician will conduct the following:

- Increase the number of traps or baits if needed
- Monitor the facility for evidence of activity more frequently
- Exchange all broken or lost traps or baits frequently

7.3. Indicate that deviations to the procedure must be approved and recorded.

7.4. The QA Technician or Pest Control Technician shall keep record of all corrective action/s or deviations as well as the cause of the problem, on the Pest Control Monitoring Record.

7.5. Identify the person to whom the final results should be reported to.

Reference documents:

4.13.85. Annex 1: Form – Pest Control Inspection Record

4.13.85. Annex 2: Form – Pest Control Monitoring Record

4.13.85. Annex 1: Form – Pest control inspection record

Form				
Pest Control Inspection Record				
Form No.:	Revision No.:	Effective Date:		
Date:	Location checked	Signs of pests [Yes/No]	Action taken	Signature

4.13.85. Annex 2: Form – Pest control monitoring record

Form					
Pest control monitoring record					
Form No.:	Revision No.:	Effective Date:			
Date:	Location checked	Types of baits/traps	Evidence of infestation	Action taken	Signature

5

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 5: Equipment

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
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Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

Table of Contents

Chapter 5 Equipment

Introduction

Every cosmetic manufacturer should ensure that equipment (for production, quality control, mechanical, electronic, automated, or chemical) is designed specifically for its purpose, whether used for manufacture, testing of components, in-process and/or finished devices. The equipment should cater for reliable and accurate results. All equipment should only be operated by trained staff and should be calibrated according to standard.

Principle

All equipment and apparatus used for the manufacture of cosmetics must be fashioned of rigid and suitable material, correctly designed, safe and simple to operate to serve its purpose. The main factors to be considered in equipment is design, location, means for sanitation, maintenance and installation. Equipment should be designed in such a way to prevent contamination of subsequent batches of products, the environment and personnel and vice-versa.

Scope

This chapter addresses steps to ensure that cosmetic manufacturing equipment and laboratory apparatus operate within the parameters necessary to produce a product that meets all specifications.

Purpose

The main goal of the chapter is to ensure that equipment employed for cosmetic production is made from stable and adequate material, correctly designed, safe and easy to operate.

Equipment design

All cosmetic manufacturing companies must verify, conduct, control and monitor production processes in such a way that the resulting product meets all specifications. The frequency of maintenance and regularity of calibration of certain equipment will be based on the type of equipment, frequency of use and the significance of the equipment during the manufacturing process.

Further detailed descriptions:

- The design of the equipment should be convenient and easy to clean
- The design may not affect the product through rust formation, leaking valves etc.
- Surfaces may not be adsorptive, additive or reactive
- The equipment should be made from non-flammable material
- All pipelines and pipes which are permanent and are utilised to transfer materials or products should be distinctly labelled with an indication of contents and direction of flow
- Water, pressure, steam and vacuum pipelines must be installed in such a manner that they can be easily accessed and should be clearly identified/labelled
- The quality and quantity of the material should be monitored and checked regularly.



Installation

Equipment should be installed in such a way as to minimize congestion. It should be correctly labelled, and it should be easy to reach during all stages of operation. Installation should be conducted in such a way as to avoid cross-contamination or build-up of dirt and dust. The layout of the installation should minimize the risks of error, it should allow effective cleaning as well as maintenance. No liquid products may be transported through flexible hoses unless the material for the hose is sturdy enough and compatible with the product used i.e. detergents, disinfecting agents and steam. Most pipelines should be in stainless steel since it is stable when in contact with materials such as hot sanitation and disinfection.

Calibration

Automatic, mechanical, electrical equipment and other equipment including computers or related systems, which correctly serves its purpose, should be used in the manufacture, processing, packing and holding of a cosmetic product. This equipment shall be routinely calibrated, inspected and checked according to a written program. The program should be designed in such a way as to ensure proper performance of all cosmetic manufacturing equipment and written records of these calibration checks and regular inspections should be done.

What is calibration?

Calibration is the practice of comparing the response of a selected instrument or system to that of a standard instrument or system over a certain measurement range. Calibration of manufacturing equipment should always be conducted to maintain the accuracy and precision of measurements. This will ensure the utmost level of confidence in all measurements concerning the material's disposition and ensures an unbroken chain of traceability according to GMP standard. In addition, it will simplify the process of determining when an equipment is no longer fit for its intended use. Components in these instruments age with time and the quality of performance will degrade, thereby making test results unreliable.

Cleaning and sanitation

The cosmetic manufacturer ensures that there is an adequate cleaning and sanitation program in place which includes all equipment and devices in the production house. This should include CIP (Clean In Place) or SIP (Sanitise In Place) procedures if required, and includes especially large or heavy immovable machines or equipment in the production house. The program should specify the correct cleaning and sanitising agents which are to be used. The effectiveness of the cleaning agents used should be confirmed. All equipment or machines which are used in continuous production should be sanitised regularly. Equipment and machines which are not used immediately after cleaning must be dried and stored in a clean safe environment to avoid

rust build-up and micro-organism contamination. Intervals for sanitisation of equipment in continuous production and equipment not used regularly, may differ depending on the requirement and where successive batches of the same product are produced. All sanitation and cleaning procedures as well as the schedules for periodic cleaning and sanitization of discontinuous (equipment not used regularly) and the regular cleaning and sanitation of continuous production equipment, should be documented accordingly.

Consumables

In compliance with GMP standard 22716, it should be ensured that all consumables used for equipment do not affect the quality of the manufactured product.

Equipment Maintenance

All equipment used in the production of cosmetics should be maintained, cleaned and adhered to according to change control schedules. Failure to do this could lead to equipment not functioning properly and thereby affecting the quality of the product.

An adequate system for maintenance, cleaning and adjustment of equipment requires the following:

- A written schedule is available
- Where adjustment is necessary to maintain proper operation, special instructions should be available
- Maintenance activities are documented
- Periodic checks should be conducted
- Activities and inspections are documented.

Ensure smoothness of the surfaces and joint finishes. The equipment should minimise ridges or crevices. Where possible joints should be continuously welded, sharp edges, screws and reverts should be avoided where possible.

Avoid presence of internal cavities where cosmetics material can accumulate.

Clearly label fixed pipework to indicate the contents and, where applicable, the direction of flow.

Authorisation

In compliance with GMP standard 22716, it is imperative that the equipment or production systems and control systems used in production and monitoring / (control) are accessible to trained and authorised personnel only. A control change system should be in place where deviations from procedure or, alterations to any material, product, facility/apparatus, process/procedure, and systems in purchasing, manufacture, quality control, research/development, marketing authorization, sales, contract manufacturing and external testing places, excluding changes to printed packaging materials, are defined. The control change request should be discussed and signed off by the appointed CCC (Change Control Committee).

Backup systems/ Redundancies

In compliance with GMP 22716 standard, it is ensured that an alternative system (backup) is defined to have arrangements in place when failure or break-down of equipment, machinery or software occurs.

Chapter 5 Equipment Checklist

Chapter 5 Equipment Checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	5.1	**Principle**					
	5.2	**Equipment Design**					
87	5.2.1	Is equipment/plant designed in such a way as to prevent the contamination of the product?					
88	5.2.2	Are the containers for bulk and intermediate products closed?					
89	5.2.2	Are the products protected from moisture, dust and contaminants?					
90	5.2.3	Are transfer hoses and accessories cleaned / sanitised and then dried?					
91	5.2.3	Are transfer hoses and accessories used in a dry location, protected from dust, splash or other contamination?					
92	5.2.4	Is the material used in the construction of equipment compatible with products and the cleaning and sanitising agents?					
93	5.3.1	Is good drainage of the equipment / devices and plants ensured, in order to facilitate cleaning and sanitisation?					
94	5.3.2	Is/are the equipment / devices and plants placed in such a way that no risk for product quality in materials, mobile equipment and personnel is expected?					
95	5.3.3	Is reasonable access under, inside and around equipment provided for maintenance and cleaning work?					
96	5.3.4	Is the major equipment sufficiently marked and readily identifiable?					
97*	5.4.1	Are the laboratory and production measuring instruments that are important for the quality of the product calibrated regularly?					
98	5.4.2	Are the measuring instruments identified and removed from service if the calibration results do not meet the criteria?					
99	5.4.3	Is investigation undertaken in the event of unacceptable calibration results to determine whether there is any impact on the quality of the product? Are appropriate steps taken?					
100	Calibra-tion Act	Are scales and measuring instruments regularly checked?					
101	Calibra-tion Act	Are scales and measuring instruments regularly calibrated?					

Chapter 5 Equipment Checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
102*	5.5.1	Is there an appropriate cleaning and, if necessary, sanitisation programme for all equipment / devices?					
103		Are CIP / SIP procedures applied for equipment cleaning? (Cleaning In Place, Sanitisation in Place)					
104	5.5.2	Have cleaning and sanitising agents been specified?					
105	5.5.2	Has the effectiveness of the defined cleaning and sanitising agents been confirmed?					
106	5.5.3a	Is the equipment / the plant cleaned and, if necessary, sanitised at appropriate intervals during continuous production?					
107	5.5.3b	Is the cleaning / sanitisation carried out for continuous production, documented?					
108	5.5.3c	Is the equipment / the plant cleaned and, if necessary, sanitised at regular intervals for discontinuous productions, if successive batches of the same product are produced?					
109a	5.5.3d	Is the cleaning / sanitisation carried out for discontinuous production, documented?					
109b*	5.6.1	Is there a maintenance and service programme in place for the equipment / plants?					
110*	5.6.2	Is it ensured that maintenance operations do not affect the quality of the product?					
111	5.6.3	Are defective parts of equipment / plants identified, marked, excluded from use and isolated if possible?					
112	5.7	Is it ensured that the consumables / auxiliaries used do not affect the quality of the product?					
113*	5.8	Are the equipment or production systems and control systems used in production and monitoring / (control) only used by authorised personnel?					
114	5.9	Are adequate alternative systems (backup) available to continue the processes in the event of a failure or breakdown?					

References:

IKW Cosmetics GMP based on ISO 22716

Websites

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 20th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/
Last viewed 20th September 2021

WHO Technical Report Supplement 5:https://www.who.int/medicines/areas/quality_safety/quality_assurance/supplement_5.pdf?ua=1https://www.bsria.com/doc/JDdLND/
Last viewed 20th September 2021

Autogarment Textile Machine Calibration Check List: https://autogarment.com/textile-machine-calibration/
Last viewed 24th September 2021

5.4. SOP 97- Equipment calibration master plan

Calibration Master Plan (CMP) - A calibration master plan is a written document that describes the company's policy for calibration of the equipment and instruments.

Logo	**Standard format for SOP:** Equipment calibration master plan Department: _____ Policy No: _____

Company header: _____

Policy: _____

Equipment calibration: Scales

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____ Date: _____

Effective date: _____ Replaces: _____

Purpose:

This SOP outlines the procedure for monitoring the accuracy of the scales used in production and to fulfil legal requirements for regular calibration by authorities.

WHY: [Why is this procedure written?]

[Why is it being performed?]

Scope:

To ensure clear and consistent management of calibrations.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

WHO: [Who performs the procedure, who is responsible to see it is performed correctly?]

The production chemist or production technician shall be responsible for the compliance of this SOP.

Frequency: (how often should this equipment be calibrated)

According to QA (Quality Assurance), audit schedule or as required (i.e. this is often written in the equipment user's manual)

Monitoring activity:

Daily GMP Audit /Monthly GMP Audit

Material and equipment:

WHAT: What is needed to perform the test. The list should be complete and specific.

(For example, a 1 kg standard weight, this is often written in the equipment user's manual)

Procedure:

How: Clear concise step by step instructions on how to perform the procedure.

This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included if necessary.

It should include:

- Preliminary steps that must be done before beginning the actual procedure.
- Safety considerations: precautions for work with physical, chemical or biological hazards
- (Containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
- Use chronological instructions. It is sensible to number the steps so that repeat steps can be referred to rather than making the SOP very long.
- Calculations: Explanations and sample of how to do any required calculations.

Sample: (obtain directions from machine manual)

1. Every day check the accuracy of the scales on production lines and ingredient weigh-up area.
2. "Zero" the scale and then place 1 kg standard weight on the scale and record the reading.
3. If standard weight reads more than 2 grams outside its stated weight, then corrective action must be taken.
4. If the scale reads within the limits specified in step 2, then the scale passes and is released for use.
5. If the scale does not pass, take whatever corrective action is required (if necessary, refer to the manufacturer's manual or, in the case of the Excell 986 scales, use the following calibration procedure). Record the corrective action on the Daily Scales Calibration Check Form.

Calibration of the Excell 986 scales:

1. While the power is OFF, press "On/Zero" key (don't release) and press "Tare" key three times to enter offset mode.
2. Press "On / Zero" key to enter the Calibration Mode.
3. Put the full capacity mass on the scale (2 kg) and press "On / Zero" key to show "CAL 1", then the display will show "the capacity", (i.e. if the scale is 2Kg, it will show "2000g"). At this time, the calibration is finished. Then, remove the mass from the scale.

Calibration of ACS weighing scales:

While the power is on, keep pressing (CAL) for about 4 seconds. Calibrate after the weight window displays "CAL".

Press (SET), the weight window displays the weight calibrated last time.

Press (↑) and (ENTER) to input the weight you want to load. Then load the corresponding weight. Press (ENTER) to make sure the calibration finished.

Note: The high limit and low limit set in the weighing model are saved in the scale. Different unit s corresponding to different alarm range and methods. The value inputted by pressing (↑) cannot be more than the full scale.

Reporting:

What next:

- Indicate where the results should be recorded.
- Explain what to do if there are problems during the test.
- Indicate that deviations to the procedure must be approved and recorded.

Identify the person to whom the final results should be reported to.

Corrective_actions:

When findings deviate from written standards, the QA designate will document findings on the Daily / Monthly GMP Audit Form and notify the General Manager of the deviation.

Short term action will be initiated and recorded on the Daily / Monthly GMP audit form. Should long term action be required, it will be discussed by management and corrective actions / responsibilities and time frames will be agreed and documented.

Deviations:

Instruments/equipment that do not meet the calibration criteria should not be used.

Deviations from approved standards of calibration on critical instruments/equipment should be investigated to determine if these could have had an impact on the quality of the manufactured products, using the data of the last successful calibration.

References documents:

5.4.97. Annex 1: Label – Equipment calibration status
5.4.97. Annex 2: Label – Equipment calibration identification
5.4.97. Annex 3: Label – Equipment calibration void status
5.4.97. Annex 4: Label – Equipment calibration void status
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5.4.97. Annex 8: Form – Discarded equipment
5.4.97. Annex 9: Form – Equipment calibration date record
13.2. SOP.322 – Corrective actions and preventive actions (CAPA)
15.0. SOP 338 – Change control procedures

5.4.97. Annex 1: Label – Equipment calibration status

Typical calibration decals have a write-on surface. A tough paper or cloth stock and a pressure sensitive adhesive are used for easy application and removal of decal.

Calibration status

Instrument: _____

Code: _____ Model: _____

Frequency: _____

Done on: _____ Due on: _____

Status: Instrument found satisfactory for analytical use

Done by: _____ Checked by: _____

Date: _____ Date: _____

5.4.97. Annex 2: Label – Equipment calibration identification

The Calibration Identification Number or its equivalent is usually the minimum information that may be on the equipment. This information allows the manufacturer to read by finding the associated calibration record/card/file.

CALIBRATION ID NO.

_____

_____

_____

5.4.97. Annex 3: Label – Equipment calibration void status

A seal or protective cover for exposed, recessed calibration controls on instruments. The calibration control cannot be adjusted without breaking the seal or removing the instrument case.

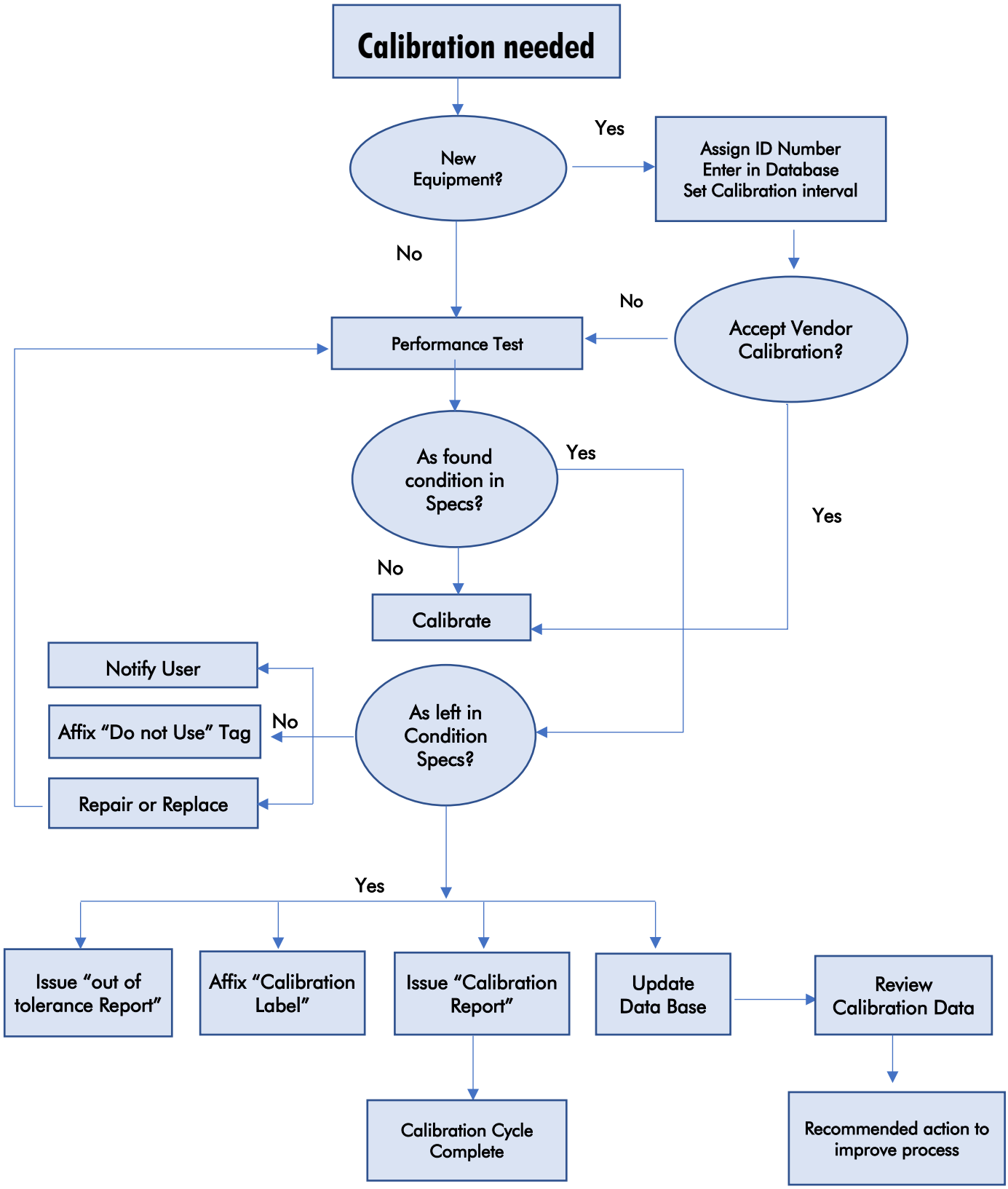
5.4.97. Annex 4: Label – Equipment calibration void status

Measuring equipment that is not calibrated or otherwise unsuitable for use should be placed in a quarantine area or labelled with a "calibration void" decal.

5.4.97. Annex 5: Label – Equipment calibration void status

A decal to be applied to measurement or monitoring instrument not intended for use in determining conformance to product master record specifications with respect to testing, manufacturing, environmental control, etc.

5.4.97. Annex 6: Flow chart – Equipment calibration process



5.4.97. Annex 7: Form– Instrument master list

Instrument List Master	
Serial number:	
Location:	
Accuracy required:	
Range of measurement:	
Calibration done date:	
Due date for next calibration:	
Calibration certificate number and Date:	

5.4.97. Annex 8: Form – Discarded equipment

Retired/ Discarded Equipment		
Date of unit retirement	Responsibility/authority	Reason: for retiring/ discarding of equipment

5.4.97. Annex 9: Form – Equipment calibration date record

Calibration Data Record								
Calibration date:	By whom:	Date due:	Reason for calibration:	Address of manufacturer:	Address of calibration laboratory:	Equipment specifications:	Serial number:	Comments:

5.5.SOP 102 – Equipment cleaning and sanitation programme

Logo	**Standard format for SOP:** Equipment cleaning and sanitation programme Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

WHY: *[Why is this procedure written.] [Why is it being performed.]*

The aim of sanitation measures is to eliminate all potential sources of cross-contamination from areas where product quality is at risk and minimize/control microbial activity.

Scope:

Sanitation should be carried out to prevent product contamination of equipment during the cosmetic manufacturing processes.

The scope should cover all aspects of manufacturing of cosmetic products:

- Personnel
- Premises
- Equipment and apparatus
- Production material and containers
- Products for cleaning and sanitising
- All potential sources of contamination

Responsibility:

- Production supervisor- in charge of all activities in relation to production.
- Quality Controller- must ensure that the product meets the criteria.
- [Company Name] manufacturing employees - must ensure the products are manufactured in accordance with the acceptance criteria

WHO: [Who performs the procedure, who is responsible to see it is performed correctly.]

- Sanitation and pre-operational activities must be monitored **[Specify frequency],** by **[Specify name/title, ex: supervisor, manager)]**. The information must be recorded on the sanitation record **[Specify, using the Sanitation Record template]**.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

There are two classes of cleaning compounds:

- acid cleaners, and
- alkaline cleaners

Chemical formulations for acid and alkaline compounds may vary according to the following:

- chemical dispensing method
- method of cleaning
- type of processing equipment to be cleaned

Procedure:

How: Clear concise step by step instructions on how to perform the procedure.

This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included if necessary.

It should include:

- Preliminary steps that must be done before beginning the actual procedure.
- Safety considerations: Precautions for work with physical, chemical or biological hazards
- (Containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
- Use chronological instructions. It is sensible to number the steps so that repeat steps can be referred to rather than making the SOP very long.

Calculations: Explanations and sample of how to do any required calculations

Reference documents:

5.5. 102.Annex1: Form – Equipment Sanitations Record

5.5.102. Annex 2: Form – Master Sanitation Schedule

5.5.102. Annex 2: Form – Master Sanitation Schedule

5.5. 102.Annex 1: Form – Equipment sanitations record

Equipment sanitations record

Instructions

Pre-operational assessment: Confirm production area and equipment are visibly clean before allowing production to start. If not ready put an X and take corrective action. Then check again.

Post operational assessment: Sanitation activities and completion of this record sheet must be done by **[Specify name/title of trained employee]**. When cleaning is complete, put a check in the box. If the equipment was not used, put n/a in the box. Initial and record all unmet requirements and corrective actions.

	Mon		Tues		Wed		Thu		Fri		Sat		Sun	
Concentration of sanitiser														
Area 1	**pre**	**post**	**pre**	**post**	**pre**	**post**	**pre**	**post**	**pre**	**post**	**pre**	**post**	**pre**	**post**
Equipment 1														
Equipment 2														
Equipment 3														
Area 2														
Equipment 1														
Equipment 2														
Initials:														
Deviations:														
Corrective actions:														

5.5.102. Annex 2: Form – Master sanitation schedule

Master Sanitation Schedule

All equipment that does not have to be cleaned daily **[Specify, ex: after each use]** must be included on the schedule to ensure that it is cleaned when needed or required.

M = monthly; **Q** = quarterly; **S** = semi-annually; **Y** = yearly Year: _____

Instructions: initial and date the columns when the cleaning is completed.

Item	Freq	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Area 1													
Mixing instruments	Y												
Fixtures	Y												
Oil pressing machines	M												
Decanter	S												
Nutcracker	Q												
Equipment 1													
Equipment 2													
Area 2													
Labelling machine	Y												
Packaging machine	Y												
	M												
	Q												
Area 3													
Area 4													

5.5.102. Annex 3: Form – Sanitation list of chemicals

List of chemicals			
Chemical	**Supplier**	**Used for**	**Approval [recommended]**
ZZZ Detergent	Kleen Co.	Cleaning all equipment and utensils	Inspection Agency Mar 10, 2012
YYY Sanitiser	Kleen Co.	Sanitising all equipment and utensils	Inspection Agency June 6, 2011
XXX Hand Soap	Soap Co.	Washrooms, floors, sinks	Inspection Agency June 6, 2011

5.6.109 Maintenance and servicing programme

Logo	**Standard format for SOP:** Equipment cleaning and sanitation programme Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this form is to lay down the procedure for sampling of finished goods during the manufacturing process.

Scope:

This SOP shall be applicable to the Quality Control Department.

WHEN: *[Indicate when this procedure needs to be performed.]*

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Assurance supervisor shall be responsible for the upkeep/continuance/completion of this document.

Accountability:

Quality Assurance Manager/Head

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

How: Clear, concise step-by-step instructions on how to perform the procedure.

This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included, if necessary.

It should include:

a) Preliminary steps that must be done before beginning the actual procedure.
b) Safety considerations: Precautions for work with physical, chemical or biological hazards (Containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
c) Use chronological instructions. It is sensible to number the steps so that repeat steps can be referred to rather than making the SOP very long.

Calculations: Explanations and sample of how to do any required calculations.

Reference documents:

5.6.109. Annex 1: Maintenance Schedule

5.6.109. Annex 2: Maintenance Log

5.6. 109.Annex 3: Form - Cosmetic Processing Equipment Programme

5.6. 109.Annex 4: Form - Cosmetic Packaging Equipment Programme

5.6. 109.Annex 5: Form - Cosmetic Storage Equipment Programme

5.6. 109.Annex 6: Form - Cosmetic Factory Cleaning-Equipment Programme

5.6.109. Annex 1: Maintenance schedule

Maintenance schedule
Company title: _____ Company logo: _____

Schedule date	Schedule for month / year	Specific unit / location / area, if applicable	Prepared by	Signature

Date *(of maintenance)*	Equipment name	Serial no.	Parts in scope – Maint. schedule *(which part needs care)*	Frequency *(yearly, monthly etc.)*	Service engineer name	Status

5.6.109. Annex 2: Maintenance log

Maintenance of equipment and apparatus cosmetics			
Company header:			
Policy:			
Equipment Maintenance Log			
Name of equipment:		Manufacturer's contact details:	
Label:		Date of purchase:	
Serial number:		Person responsible for equipment:	
Manufacturer:		Date put into service:	

Date:	Maintenance description:	Maintenance performed by:	Date of validation before put into service:	Validation performed by:	Next maintenance planned on (date):	Remarks:

5.6. 109. Annex 3: Form - Cosmetic processing equipment programme

Cosmetic processing equipment programme						
Name of equipment:	Frequency:	Item no.:	Type of maintenance:	Approved by:	Signature:	Date approved:
Scale/balance						
Ph meter						
Infrared thermometer						
Sets of beakers						
Scrapers						
Homogenizers						
Heating elements/plates						
Mixing equipment						

5.6. 109. Annex 4: Form - Cosmetic packaging equipment programme

Cosmetic packaging equipment programme						
Name of equipment:	Frequency:	Item no.:	Type of maintenance:	Approved by:	Signature:	Date approved:

5.6. 109.Annex 5: Form - Cosmetic storage equipment programme

Cosmetic storage equipment programme						
Name of equipment:	Frequency:	Item no.:	Type of maintenance:	Approved by:	Signature:	Date approved:

5.6. 109. Annex 6: Form - Cosmetic factory cleaning-equipment programme

Cosmetic factory cleaning equipment programme						
Name of equipment:	Frequency:	Item no.:	Type of maintenance:	Approved by:	Signature:	Date approved:

5.6. SOP 110 - Equipment operation training programme

Logo	**Standard format for SOP:** Equipment operation training programme Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

[Insert company title] is committed to providing a safe working and learning environment. It aims to produce a reliable product in terms of quality and GMP standard. The purpose of this procedure is to ensure that all staff members are aware of safe and correct operating procedures for the equipment they may or will be working with.

Scope:

This standard equipment operating procedure applies to any [insert company title] employee who will be operating or teaching trainees to operate any piece of equipment, as well as trainees who operate the equipment.

WHEN: [Indicate when this procedure needs to be performed i.e. when the procedure will come into effect.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

WHO: Technologists/Technicians are responsible for overseeing that all the necessary documentation is in order. This includes maintenance sheets, pre-inspection sheets, SOP's and completed training sign-off sheets. The Supervisor will be responsible for the training delegation.

Who performs the procedure, who is responsible to see it is performed correctly.

Material and equipment:

WHAT: What is needed to perform the test. The list should be complete and specific.

Procedure:

[NB: the operating procedures of most equipment can easily be obtained from the User's manual of the equipment]

How?

Clear concise step-by-step instructions on how to perform the procedure.

This should be written as instructions for the operator to follow, without a lot of theoretical background. A section on fundamental principles can be included if necessary.

It should include:

- Preliminary steps that must be done before beginning the actual procedure.
- Safety considerations: Precautions for work with physical, chemical or biological hazards
- (Containment facility clothing, tasks, hoods, goggles, gloves, clean-up of spills etc.).
- Use chronological instructions. It is sensible to number the steps so that repeat steps can be referred to rather than making the SOP very long.
- Calculations: Explanations and sample of how to do any required calculations.

Reporting:

WHAT NEXT:

- Indicate where the results should be recorded.
- *[i.e., the results should be recorded on the training completion sheet and signed-off by the correct authority].*
- Explain what to do if there are problems during the equipment operation.

Corrective Action

All deviations must be reported and signed-off by the technologist/technician before proceeding.

- Indicate that deviations to the procedure must be approved and recorded.
- Identify the person to whom the final results should be reported.
  [i.e., the technologists/technician].

ENFORCEMENT: Employees who fail to comply with this procedure will be subject to the discipline policy which may result in a written warning, suspension and/or subsequent termination of the employment contract.

Reference documents:

List other SOPs which directly affect or are relevant to this procedure. For example, the SOP for making a buffer used in the procedure, or the SOP for the operation of a piece of equipment used in the procedure.

5.6.110. Annex 1: Form – Personnel training record

Company header **Personnel Training Record**	
Date:	
Trainer:	
Signature of trainer:	
Training done:	
Materials presented: (Specify training materials, ex: policy/procedures, demonstrations, videos, presentations etc.)	
Employee name:	Employee signature:
*The employee signature indicates they have received and understood the information presented and will comply with the policies or procedures.	
Date prepared: *(Date the policy was prepared/revised)* Authorised by (manager responsible):	

Revision Log	
Revision Date:	Summary of Changes
	Developed procedure
	Policy and Procedure Committee- revisions approved
	Academic Coordinating Committee- revisions approved
Policy: All personnel should receive adequate training in Good Manufacturing Practices, equipment safety operations and operating procedures. A personnel training record should be kept of all training done.	

5.6.110. Annex 2: Form – Pre-use equipment inspection checklist

Pre-use Equipment Inspection checklist							
Date:				Model:			
Item title:	Item no.:			Supervisor:			
✓For sufficient, ✕ For requires attention (tick the appropriate box below)							
	Sun	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Visual checks operators #							
General condition of equipment							
Housekeeping of the area - is the floor clear of obstacles							
Fire extinguisher present							
Check overhead obstacles or obstructions							
Battery: charged, check cables, connections not loose							
No fluid leaks, damage, good working condition							
Operational checks							
Machine operates smoothly. No abnormal noises							
No leakages while operating							
Details on areas for attention							

5.8.113. Annex 1: Chart – Authorisations/Responsibility

Responsibilities

Quality Assurance (chairperson):

- Calling the CCC meetings and taking minutes
- Coordination of circulation procedures
- Maintenance of the database of change control procedures
- Formal control of the change requests
- Monitoring compliance with deadlines
- Archiving the completed change requests

Change Control Committee

- Risk evaluation of the change request
- Authorisation or rejection of the application
- Establishing and scheduling necessary measures

Sales Manager:

- To achieve sales target
- To be an expert in technical and marketing knowledge
- Ensure that the batch and its manufacture comply with the provisions of the marketing authorisation
- Ensure that changes requiring variation to the marketing authorisation have been notified and authorised by the relevant authority

Head of Regulatory Affairs:

- Ensures that product complies with the GMP standard and company/government regulations

Head of Production:

- Products produced and stored according to requirements
- Approval of production instructions and their strict implementation
- Ensure production records are evaluated prior to sending to QC
- Maintenance of department, premises and equipment
- Validations performed
- Initial and on-going training

6

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 6: Raw Material and Packaging Material

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
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Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
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Revised:			

Table of Contents

Chapter 6 Raw Material and Packaging Material

Introduction

This chapter focuses on the analysis and documentation of raw materials and packaging materials. When it comes to the assessment of new suppliers, it is advisable to carry out a comparative analysis on various supplier batches of raw materials by using the "quantitative risk management" strategy. The cosmetics manufacturer should ensure that the supplier of the raw materials presents a certificate of analysis of the raw material which they supply. All certificates should be filed in the cosmetics product information folder. All requirements for raw materials and packaging materials must be suitably recorded. This includes detailed conditions of acceptance relevant to the quality of the finished products. All open containers, vessels or sacks used for raw materials and packaging materials must be properly sealed while in storage to minimise the risk of contamination. Where municipal water is used during the production process, it is imperative that the water quality is regularly tested. As an alternative, freshly boiled and subsequently cooled deionised mineral water could be used during cosmetic production. Another important factor to consider in this chapter is the establishment of a well-organised tracking system which will assist in monitoring the handling of raw materials and packaging materials. One method is to use labels to identify and determine the status of each batch and lot of raw materials and packaging materials used in cosmetic production. A new label may replace an old label, thereby eliminating the previous status of the product. Random sample testing of raw materials and packaging materials should be conducted regularly to ensure product safety. The areas for labelling and packaging should be clearly marked and easily identifiable to avoid confusion. It is a requirement that no finished product be released without the approval of Quality Control.

Objective

The purpose of this chapter is to ensure that all materials used during production have met the GMP criteria and ensure the quality of the final product. It will also eliminate the likelihood of confusion by establishing a suitable labelling system for raw materials and packaging material. The documentation on these labels facilitates batch or lot tracking of each item used in cosmetic production. Raw materials and packaging materials in storage need to be regularly tested and any discrepancies investigated.

Scope

This chapter focuses on the ISO 22716 GMP (2007) requirements of all raw materials (including water) and packaging materials relevant to the cosmetic manufacturing processes. This includes subsections for requirements relevant to: receipt, purchasing, identification and status, release, storage, re-evaluation and the quality of water used in production. Some of the criteria that a cosmetic manufacturer should consider with regards to this chapter are:

1. Do you have a storage system set-up in such a manner that it will reduce mix-up, spoilage and damage to your stock?
2. Do you clearly and accurately label stock?
3. Do you have measures in place to confirm that the water used in your cosmetic products is sterile, hygienic, uncontaminated and of a specific quality (for example purified water of USP or Ph. Eur.)?

Principle

The main principle behind this chapter is to minimise the risk of mix-ups and cross-contamination with regards to raw material and packaging materials in cosmetic production. Moreover, the principle of focus here is to be able to track down and address any discrepancies found in a certain batch or lot and apply stock inventory of all cosmetic manufacturing ingredients. The incorporation of all the above will ensure that each manufactured product maintains the same standard and quality.

Purchasing

The cosmetics manufacturer should ensure that all stock used in production was purchased from evaluated and selected suppliers. The technical clauses regarding the criteria for acceptance, actions on deviations and transport conditions should be arranged with the key suppliers. This is to avoid product deterioration and ensure that the proper conditions such as temperature requirements are taken into consideration when transporting and storing the product. In addition, regular audits and questionnaires for the key suppliers should be maintained. However, it is possible to outsource audits to an external company or organisation.

Receipt

The cosmetic manufacturer under GMP conditions (aka GMP manufacturer) must ensure that written records are kept for the receipt of each delivery of initial and primary printed packaging material. An appointed staff member should be tasked with checking that the purchase order, delivery note and delivered materials correspond with the order/delivery. The appointed staff member should also examine the sound and undamaged state of the containers before accepting the purchase or delivery. Where applicable, the appointed staff member should check the purchase or delivery based on any additional transport data which is required, e.g. temperature requirements during transport.

Identification and status

Incoming goods with visible defects that might affect product quality should be retained pending a decision on their use.

The GMP manufacturer should ensure that materials are identified with the following:

- Name of producer/recipient
- Company name
- Date / number of receipt
- Supplier‘s name
- Batch references, incl. production and best before dates
- Container number
- Container amount
- Container gross / tare weight.

Release

The term “released” is defined as the status of initial materials, intermediate materials and bulk or finished products which have been permitted and authorised for use in processing, packaging or distribution. The cosmetic manufacturer must note that a system has been set up to ensure that only the raw and packaging materials which have been “released” are utilised for processing, packaging and distribution. Materials may

be approved for "release" if it is in accordance with the supplier certificate, it meets the requirements, surpasses the agreed test methods and supplier audit.

Storage

The main purpose of this section is to ensure that when the finished product arrives at the consumer, it will be safe to use and of good quality. GMP with regard to storage consists of five components:

- warehouse
- storage facilities
- personnel
- management and control
- documentation.

The warehouse and storage facilities should be designed according to their intended purpose, approved and suitable. The correct building material for the infrastructure should be used to protect and store the product. The building/infrastructure should be well-maintained and secure. There should be enough space to allow for free flow, to minimise the risk of mix-ups or damage to materials and products. The storage areas are required to be well-organised with segregated and labelled areas specifically dedicated to sampling of initial materials to avoid contamination. Where applicable, the storage area should cater for temperature and humidity control. The temperature should be as per recommendation on the product's label. The environmental conditions of the storeroom should ensure the safety and quality of the product. A written pest control program should be implemented and records thereof filed. All equipment and products should be handled by qualified personnel who are healthy and adhere to hygienic methods, and have been provided with the applicable training for the job e.g. store- or warehouse management, inventory, safety, hygiene, good housekeeping, control system, documented procedure etc. The store management control personnel will be in charge of receiving and identifying stock, do stock control, product release and repackaging and transportation as well as product disposal. A FIFO ("first-in" - first out") method should be followed when product release is conducted. This means that products should be sold in the order of the oldest product first. End products should always be rechecked before delivery and monitored during transport and delivery. No containers should be stored on the floor. The repacked materials should carry the same labelling as the original one.

Re-evaluation/re-testing

The main function of allocating a re-evaluation date to cosmetic production material is to check the material and analyse it in relation to the manufacturing recommendations or in-house procedures. This will ensure that the material being stored always meets approved specifications before re-used or re-incorporated elsewhere in the production. The expiry date marks the end of the period in which the material can be utilised and is the limited term of that product's validity.

Storage material should be re-evaluated after a specified (documented) time. If stock is held back and separated for later use in production operations, it should be stored in a suitable container and identified with the following information available: Title of material or item code; control or receiving number;- weight and re-test or re-evaluation date if appropriate. Goods should be re-evaluated, as per requirement to their suitability for use (e.g. after lengthened periods of storage or exposure to heat or humidity).

Quality of water used in production

Special attention should be paid to water since it is an important raw material and will influence the quality of the end product. Water production equipment and water systems should supply quality water. Water systems should be sanitised according to well-established, normed procedures. The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action. The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained. The cosmetic manufacturer should ensure that there is a specified and controlled system for checking the quality of raw materials prior to use. Once the raw material has been checked it should be labelled according to the status of the material, being either “Release” or “Quarantine” or “Rejected”. All raw materials are stored in sealed and correctly labelled containers in a suitable location. Raw materials may not be stored directly on the floor. Water used as a raw material for production must be tested for microbiological quality on a regular basis.

Checklist: Raw material and packaging material

Chapter 6 Raw material and packaging material							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	6.1	**Principle**					
	6.1	Do all raw materials and packaging materials meet the acceptance criteria which is relevant to the quality of the finished product?					
	6.2	**Purchasing**					
118*	6.2.a.a	Is there a process in place to evaluate and select appropriate suppliers / producers of materials?					
119	6.2.a.b	Is the process for the evaluation and selection of appropriate material suppliers / producers applied to in a reliable manner?					
120	6.2b	Are there any agreements with the supplier / producer which define, for example, the type of selection to be conducted, the acceptance criteria, actions in the case of defect or modifications and transport conditions?					
121	6.2c	Do the agreements include statements on the setting up of relations such as assistance and audits by the contractor?					
	6.3	**Receipt**					
122*	6.3.1a	Is there a process to check whether the purchase order, the delivery note and the delivered materials agree?					
123	6.3.1b	Are any additional checks made in respect of the identity of the producer?					
124	6.3.2	Are the shipping containers checked visually for integrity and, if necessary, additional checks on transport data performed?					
125		Are all incoming goods subject to defined sampling?					
126		Is sampling equipment prescribed for all raw materials?					
127		Is the prescribed or defined sampling equipment adequate for raw materials to secure their quality control results?					
	6.4	**Identification and Status**					
128	*6.4.1	Are the raw materials provided with labels which contain information on the supplier / producer, identity and badge?					
129		Are the raw materials labelled with information on the container number, amount, gross / tare weight?					
130	6.4.2	Are incoming goods with visible defects that might affect product quality,					

Chapter 6 Raw material and packaging material							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
		retained, pending a decision on their use?					
131	6.4.3	Are the materials identified physically as "accepted", "rejected" or "quarantined", or, is this ensured by another system with the same level of assurance?					
	6.4.4	**Does the material identification include:**					
132	*6.4.4a	▪ the name of the product of the supplier / producer and recipient (if different)?					
133	6.4.4b	▪ the date of receipt?					
134	6.4.4c	▪ the name of the supplier and producer (if different)?					
135	6.4.4d	▪ the batch reference of the supplier / producer and recipient (if different)?					
	6.5	**Release**					
136	*6.5.1	Are there any physical or alternative release systems?					
137	6.5.2	Is the release carried out by authorised personnel responsible for quality?					
	6.5.3	**If releases are based partially or as a whole on supplier certificates, have in this case:**					
138	6.5.3a	▪ the technical requirements of the supplier been assessed?					
139	6.5.3b	▪ the experience and knowledge of the supplier been assessed?					
140	6.5.3c	▪ audits been carried out at the supplier?					
141	6.5.3d	▪ test methods been agreed with the supplier?					
	6.6	**Storage**					
142	6.6.1 / 6.6.2	Are the storage conditions appropriate for the materials?					
143	6.6.3	Are specific storage conditions respected and monitored?					
144	6.6.4	Are the materials stored closed and off the floor (e.g. on pallets)?					
145	6.6.5	Are newly and / or repacked materials provided with the same labelling as in incoming goods?					
146	6.6.6	Are rejected materials and / or materials in quality tests stored in a separate / identified location and / or managed by a corresponding data system?					
147	6.6.7	Does the FIFO principle (First In - First Out) apply for the use of the materials?					

Chapter 6 Raw material and packaging material							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
148	*6.6.8a	Are inventories performed on a periodic level?					
149	6.6.8b	Are significant discrepancies investigated after inventories and is corrective action taken, if necessary?					
	6.7	**Re-Evaluation**					
150*	6.7	Is an adequate system used to re-evaluate and assess the materials after a defined period of storage?					
	6.8	**Quality of Water Used in Production**					
151	6.8.1	Does the water treatment system supply the defined quality of water?					
152*	6.8.2a	Is the water quality regularly monitored / tested?					
153*	6.8.2b	Are monitoring / testing measures and all results documented?					
154	6.8.3	Can the water treatment system be sanitised?					
155	6.8.4	Is a permanent circulation ensured in the water treatment system (reduction of the contamination risk)?					
156	6.8.5	Is it ensured that the materials used in water treatment do not influence water quality?					
157		Is it ensured that the materials used for water treatment do not affect the product quality?					

References: IKW Cosmetics GMP based on ISO 22716

Reference Websites:

A WHO guide to good manufacturing practice (GMP) requirements: https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1: Last viewed 22nd August 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/ Last viewed 22nd August 2021

SOP handling of returned goods: https://pharmastate.blog/handling-of-returned-goods/ https://pharmabeginers.com/handling-of-returned-goods/ : Last viewed 22nd August 2021

SOP for Product Recalls: https://www.pharmaguideline.com/2012/07/sop-for-product-recall.html Last viewed 22nd August 2021

6.1.115, 116 and 117 – Specifications

[refer to product specifications documents in "chapter 7 Production"]

6.2.118 – Evaluation and selection process of supplier/producer

[refer to contract manufacturing agreement procedures and documents in "Chapter 12 Subcontracting/services and contract manufacturing]

6.3.122. Annex 1: Form – Record of receipt

NB: There should be a written record for the receipt of each delivery of each starting and primary printed packaging material.

[refer to " Returns" and "handling of returned goods" in "Chapter 8 Finished Products"]

Record of Receipt	
Name of supplier:	Date of receipt:
Manufacturer's batch/reference number:	
Total quantity of containers received:	Number of containers received:
Batch number: (assigned after receipt):	
Comment: (e.g. state of containers):	

6.4. 128 and 132. Annex 4: Labels - Product identification labels, Rejected, Blocked, Released

Product Identification Labels: [NB: It is best to make use of a colour-coding system for the labels e.g. green: released, yellow: blocked, red: rejected.]

[refer to batch numbering and labelling system in "Chapter 7 Production"]

Company Logo	Title	Quality Department
Released		
Date:	Signature:	

Company Logo	Title	Quality Department
Blocked		
Date:	Signature:	

Company Logo	Title	Quality Department
Rejected		
Date:	Signature:	

Company Logo	Title:
Product Name:	Supplier Name:
Produce Name:	Recipient Name:
Date:	Batch Reference:

6.5. 336. Annex 2: Form – Product release form

Product Release Form			
The following product is available for release to the market			
Product:			
Batch no.:		Batch size:	
Mfg. date:		Expiry date:	
Packing details:		Number of intact:	
Loose pack:		Number of loose packed:	
Total Qty. released:		Total number of packed released:	
Quality control number:		Date:	
Reference number:			
Prepared by:		Checked by:	
Released by:		Format number:	

6.7. 150. SOP - Re-evaluation/retesting

Logo	**Standard format for SOP:** Re-evaluation/Retesting Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To ensure compliance with the storage and approval of raw material at regular intervals

Scope:

This procedure is applicable for approved active and inactive raw material which are stored in the raw material warehouse.

This procedure is applicable for approved active and inactive raw material which are stored in the raw material warehouse.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Carrying out of task: Technical Assistant

Checking: Executive/Manager

Accountability:

Head of Department

Procedure:

1. Re-evaluation shall be referred to as the date beyond which the material may not be utilised without retesting, unless the material has already expired.
2. Whenever the manufacturer claims that the material is to be re-evaluated after a certain date, consider the date/interval. If it is less than the retesting date mentioned by this SOP, follow this SOP for assigning a new retesting date.
3. In the event where manufacturer provides an expiry date, the retest period shall be as follows:
4. In the event where the retest material is provided with a retest date, contact the manufacturer for stability data to extend the shelf life of the material.
5. Basis on which a retest shall be conducted:

5.1. Active raw material: 1 year from initial date of release.
5.2. In-actives: 2 years from the initial date of release (includes solvent flavours).
5.3. Enzymes and vitamins: 6 months from initial date of release.

6. Based on the terms used by the manufacturer, if it does not indicate the expiry date, it shall be taken as retest date.
7. Retesting shall be continued up to the expiry data provided by the manufacturer or, 5 years from the expiry date when manufactured, whichever is the earliest.
8. Sampling procedure for retesting: [insert the steps for your company's procedure for retesting of raw materials]
9. For raw materials under retest, sampling shall be performed as per above mentioned sampling procedure and collected from each available container, and placed in a polythene bag, to make a composite sample.
10. Retest samples shall be labeled as per retest sample label. After sampling, relevant details shall be documented in, "6. 150.Annex 1: Form – "Record of Receipt"
11. For retesting materials, the following test shall be performed:
    11.1. Description of the material (Physical appearance)
    11.2. Assay (this is a laboratory test that identifies and quantifies the presence of certain chemicals or substances. Depending on the product and requirement, pharmacological laboratories may conduct certain types of assays e.g. probe-based assays or cell-based assays
    11.3. Chromatographic impurities or related impurities (if applicable)
    11.4. Loss on drying/ water content
    11.5. Microbial limit test (if applicable)
12. After analysis, if the material is approved, the retest label is affixed.
13. If the material does not meet the specifications, investigate through OOS (Out of Specifications) procedure or other QMS (Quality Management System) Tools.

References documents:

6.150.Annex 1: Form – Record of Receipt

8.5 Returns: SOP 231- Handling of returned goods

10.1. OOS: SOP 272 - Investigation of Out of Specification products and materials

6.8.152. SOP - Quality of water used in production

Logo	**Standard format for SOP**: Quality of water used in production Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Materials and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Prior to use, the QA manager shall ensure that all starting materials are verified.
2. The QA manager shall ensure that the verification includes a review of the Certificate of Analysis from the manufacturer and compare it with the approved specification.
3. Where necessary, the QA manager shall conduct an identification test and other examinations on the characteristics of the material.
4. Primary packaging should be examined for leaks, sharp dents, tears, exposed parts and seal integrity.
5. The QA manager shall conduct checks to ensure that the packaging label, batch number and identification numbers are clear and correct.
6. The QA manager shall allocate the frequency of tests and checks for each manufactured batch.
7. The standard for drinking water shall be defined as the “minimum standard” for use in cosmetic processing.
8. The QA manager shall ensure that the specification for microbial and chemical quality is based on the point or purpose of use.
9. Based on the requirement, the QA manager shall ensure that water quality tests are conducted on a weekly/monthly basis.

10. Depending on product formula, process and claim requirements, further treatment may need to be implemented. In the case of further treatment, the QA manager must base the specifications for water quality on the supplier design specification or the pharmacopoeia standard.
11. The cosmetic manufacturer must carefully review the quality of the water to be used. This is important when water comprises most of the product content. Water is the fundamental raw material used in many cosmetic formulas. As a result, the choice of water quality will greatly impact the quality and stability of the final product.
12. De-ionised water should be utilised for products that may be applied near to the eye area, mucus membrane and oral cavity as well as for products for babies.
13. The cosmetic manufacturer must ensure that water quality meets the standards for national or WHO drinking water.
14. The QA shall ensure that the treated water specification is established based on the supplier's design specification or the pharmacopoeia standard.

Definitions:

References documents:

8.5 Returns: SOP 231- Handling of returned goods

Other related documents: *(these documents may also be found in their respective chapters according to the title and number)*

8.5 Returns: SOP 231- Handling of returned goods

Logo	**Standard format for SOP**: Handling of returned goods Department: _____ Policy No: _____

Company header: _____

Policy: _____

Handling of returned goods

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The objective of this SOP is to define the procedure for the handling of returned goods, remedying and repacking.

Scope:

This procedure is applicable for remedying, handling and repacking of finished goods by reason of shelflife extension, renewed price or price adjustment and returned goods from any other location or retail.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

For example:

1. It is the responsibility of the **Warehouse Personnel** to do the following:
    - To notify the QA and production departments regarding receipt of finished goods.
    - To maintain the records of returned goods.
    - Check all documentation and the condition of the returned goods.
    - Ensure that the goods are stored correctly in accordance with the recommended requirements.
2. It is the responsibility of the **QA Personnel** to do the following:
    - Verify the physical status of returned goods and make sure that the laydown protocol is followed in accordance with SOP.
    - Provide a batch packaging record when applicable to rectifying/remedying or repacking of finished goods, as well as returned goods.
    - And to withdraw the control sample.
    - Ensure that the batch is released once all packing activities are done.
3. **Quality Control Personnel** are responsible for the investigation of the returned goods as per recommendation by the QA Head.
4. **Production Personnel** are responsible for:
    - Establishing a packing plan as per the requirements received by the QA Head.

- Provide a bill of material.
- Work order.
- Maintenance repair operation where applicable.

5. The **Plant Head and Quality Head** shall be responsible for the review and approval of the SOP and to ensure the compliance of the laydown procedure.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Procedure for handling returned goods
   - 1.1. Receipt and handling of returned goods:
     - 1.1.1. Upon arrival all returned goods shall be received by warehouse personnel.
     - 1.1.2. Materials should be stored separately in a manner suitable to the storage conditions of the respective products and in the correct designated area for returned goods.
     - 1.1.3. The area should be demarcated specifically for returned goods and easily identifiable by label or marking.
   - 1.2. Warehouse personnel should check and verify the consignment for the following information against the delivery documents which have been received.
     - 1.2.1. Identity of the product / validity of labels.
     - 1.2.2. Batch code or number.
     - 1.2.3. The number of containers/shipments received in comparison to supply.
     - 1.2.4. Condition of containers/shipment intactness and seal integrity.
     - 1.2.5. Weight and the total quantity of returned goods for containers/shippers.
   - 1.3. The physical state of the returned goods shall be carefully inspected by the warehouse official and the details shall be written in the "Returned Goods Verification Report".
   - 1.4. Warehouse personnel are required to produce a "Distribution Receipt".
   - 1.5. After completing the "Distribution Receipt" in the system and the physical verification of the returned goods, the warehouse personnel shall send the "Returned Goods Verification Report", to the QA for verification.
   - 1.6. Each shipment/batch shall be verified by the QA, who will then make a recommendation/decision based on the following:
     - 1.6.1. Whether the material is returned by reason of commercial dispute or as a result of not meeting physical specifications;
     - 1.6.2. If the material is found to be intact, and the seal number and label number correspond with the packing details, management will approve the release of the material for direct re-sale;
     - 1.6.3. If the material is returned by the customer by reason of commercial dispute or because the product does not meet the physical specifications or if the seal is broken by the customer, then the material must be verified and QA shall make a decision based on observation and as per the "Goods Verification Record";
     - 1.6.4. Where the material has been confirmed as contaminated or it is a case of sabotage, the material shall be sent for disposal or destruction according to the "Goods Verification Record";
   - 1.7. Once the physical verification of returned goods has been completed by warehouse personnel and QA:
     - 1.7.1. The warehouse staff shall be responsible for cleaning or re-packing the returned goods in line with the required conditions.
     - 1.7.2. The warehouse staff shall print the "Returned Goods Quarantine" label and attach it to each container, as per recommendation from the Head of Production and Quality Assurance in the "Goods Verification Record".
     - 1.7.3. Note: Materials to be discarded are not required to have the "Returned Goods Quarantine" label.
     - 1.7.4. The "Returned Goods Verification Record" shall be filled in by QA staff and it shall be sent to the Head of QA and the Head of Production for further recommendation.

1.7.4.1. Based on the recommendation of the "Returned Goods Verification Report", returned goods are allowed for sampling and re-analysis as follows:

1.7.4.2. If, after re-analysis, the result is found to comply with the specification parameters, then the material shall be re-packed and released for re-sale.

1.7.4.3. If the material does not comply with the specification parameters, it will be discarded as per decision in the " Returned Goods Verification Record".

1.7.4.4. Based on the recommendation of the Production Head and QA Head:

1.7.4.5. QA personnel shall forward the "Returned Goods Verification Report".

1.7.4.6. QC, in case it is recommended for sampling and re-analysis.

1.7.4.7. Packing, in case sampling and re-analysis are not required, material shall be re-packed.

1.8. Warehouse storeroom in case material is recommended for disposal:

1.8.1. QC will generate a quality control order in the system for sampling and retesting/re-evaluation if materials are recommended for re-analysis.

1.8.2. QC will complete the section in the "Return Goods Verification Report" and will perform inspection and re-testing of the products returned.

1.8.3. Once the re-analysis is complete, the material shall either be "approved" or "rejected" by the QC and all the accompanying documents, as well as the analytical documents, shall be sent to QA for further decision.

1.8.4. The QA shall thereafter send a recommendation for either "redressing" or "repacking" or "destruction" , based on the results of the analytical data and findings of the material in accordance with the "Goods Verification Record".

1.8.5. In the event where retesting is not necessary during sampling of returned goods and redressing/remedying or repacking has been sanctioned directly, then the QA shall send the "Returned Goods Verification Record" directly to the packing department.

1.8.6. If it is decided to reprocess the goods, it shall be handled through the SOP of "Reprocessing" and the manufacturing and expiry date of goods shall remain unchanged.

1.9. Returned products final utilisation must be concluded within 60 days of receipt.

1.9.1. Returned products that have been consigned for disposal shall be disposed of according to the instruction in the "SOP for Handling of Rejected Materials" in the production sites.

2. Re-packaging of returned goods:

2.1. After receipt of the "Return Goods Verification Report" from the QA officials, the packing staff shall write up the "Re-packaging Record Request Form".

2.2. Prior to packing procedures, the packing staff shall collect the returned goods from the warehouse storage area and store it in a more suitable place.

2.3. Once the date of manufacture and expiry date has been verified, the QA shall sign and authorise the release of the returned goods for re-packing.

2.4. As with the previous entries, the QA shall include any required information in the same register. Batches need to be clearly identifiable.

2.5. The re-packing procedure shall be initiated as soon as the packing official has received the batch corrective record.

2.6. It shall be recorded in the Batch Re-packing Records.

2.7. The packing officer and QA officer shall perform an in-process check during the re-packing activity.

2.8. And record the same in the Batch Re-packing Record.

2.9. Once the re-packing procedure is complete, the QA officer shall extract a Control Sample and ensure complete documentation of the Batch Re-packing Record is up to date.

2.10. After closing the Batch Re-packing Record, the QA officer shall complete the final inspection report. If found satisfactory, the QA officer shall release the batch for dispatch.

2.11. The QA officer shall check for any discrepancy found during final product inspection, it shall be discussed with the QA Head and corrective action shall be taken as per recommendation from the QA Head.

2.12. The QA shall check and review the re-packing record and release the batch.

3. Returned Goods Repacking:

3.1. Once (8. 231.Annex 1: Form) the "Returned Goods Verification Record" has been received from the QA department:

3.1.1. The returned goods shall be retrieved from the warehouse storeroom by packing personnel

3.1.2. The returned goods shall be stored in a suitable place prior to the packing operation

3.2. All repacked finished goods shall be affixed with its designated batch number and annotated with the "R" symbol.

3.3. Once packed, packing staff must ensure that returned goods are unpacked, but only in controlled areas.

3.4. Once unpacked the physical state of the packed goods shall be checked by the packing staff and QA staff to ensure that the repackaging is based on the criteria for unpacking goods.

3.5. Based on inspection and review of the bulk lot, the QA shall make the final decision for the goods to be either packed or disposed.

3.6. Should the physical state of unpacked goods be deemed faulty, it may be discarded in accordance with "8. 231.Annex 1: Form "Returned Goods Verification Record".

3.7. Should the unpacked goods be deemed up to standard, then a "Batch Packing Record" shall be requested from the QA department by packing staff.

3.8. If needed, the QA shall extract a sample for dispatch to QC laboratory to conduct an analysis together with the required report.

3.9. All unpacked goods shall be stored in the designated storage facility until it is ready for the packing process, after which it shall receive a suitable status label.

3.10. Packing staff shall make use of the Quarantine Inward/ Outward Logbook should any bulk goods be transferred to the quarantine storage facility.

3.11. "A Batch Packing Record" shall be authorised and issued by the QA once the manufacturing date and expiry date have been confirmed.

3.12. The QA department shall ensure that the "Batch Packing Logbook" is updated with each new entry.

3.13. Upon obtaining the "Batch Packing Record" the packing staff shall initiate the repacking procedure.

3.14. Prior to commencement of the packing procedure, packing staff shall conduct line clearance and prepare equipment according to the appropriate SOPs.

3.15. The packing officer and QA officer shall perform the in-process check during the repacking activity.

3.16. The above shall be recorded in the Batch Packing Record.

3.17. After completion of the repacking activity, the QA ensures complete documentation in the Batch Packing Record and withdraw the Control Sample.

3.18. After completion of "231.Annex 1: Form "Returned Goods Verification Record" :

3.18.1. The analytical results shall be attached with the Batch Packing Record.

3.18.2. The warehouse shall enter the details in the "8.231.Annex 3: Form – "Returned Goods Logbook"

Definitions:

Returned Goods:

These may entail :

- Products which do not meet the established specification for the customer, or products which do not satisfy the customer's specification.
- Products which have been returned due to damage or defective packaging, marketable or administrative factors, or as a result of customer complaint or similar.
- Withdrawal of a certain batch(es) from commercial sale, in association with the Product Recall Procedure.

Remedying (redressing):

It is defined as repacking of a material/product without disturbing its original inner origin (primary packing material) by only changing its label or external container (secondary packing material) for commercial purpose.

References documents:

231. Annex 1: Form Returned Goods Verification Record

8. 231. Annex 2: Labels – Returned Goods Quarantine Label

8.231. Annex 3: Form - Returned Goods Logbook

8.231. Annex 4: Labels - Product Identification Labels, Rejected, Blocked, Released

SOP for clearance of lines, area and equipment

8. 231. Annex 1: Form returned goods verification record

Returned Goods Verification Record			
Name of product:		Batch no.:	
Manufacturing date:		Expiry date:	
Dispatch tracking no.:		Dispatch date:	
Quantity dispatched:		Date of return receipt:	
Wt. (weight) of return qty. (where applicable):		Quantity received (no.):	
Total no. of Containers		Label authenticity:	
Seal no. (if any):		Seal iIntegrity:	
Goods returned from:			
Reason for returning:			
Condition of returned goods:			
Any other observations:			
Documents handed over to QA: *Yes/No*			
Done by:		Checked by:	
Signature:		Signature:	
Quality Assurance:			
To be packed		**Not to be packed**	
Condition:	Recommendation:	Condition:	Recommendation:
Sampling and retesting required:	*[Yes/No]*	Product is not satisfactory:	*[Yes/No]*
Only redressing is required:	*[Yes/No]*	Product shelf life is less than six months:	*[Yes/No]*
Repacking to be done without retesting:	*[Yes/No]*	Quantity is much less:	*[Yes/No]*
Any other:			
Reason for recommendation:			
Remarks:			
Recommended by: *(Production/Packing Head)*		Recommended by: *(QA Head)*	
Name:		Name:	
Signature:		Signature:	

Quality Control:					
Name of the product:			Batch no.:		
Manufacturing date:			Expiry date:		
Serial. no.	Test	Finished product analysis result	Retest analysis	% Deviation from the previous result	Remarks: (Comply/not comply)
1.					
2.					
3.					
4.					
5.					
Quality Assurance:					
Recommended by: *(Quality Assurance)*			Approved by: *(QA Head)*		
Name:			Name:		
Signature:			Signature:		
Packing:					
Product name:			Batch No.:		
Materials received from:			Quantity received from:		
Packing started on:			Packing completed on:		
Batch packing record closed on:			Date of transfer:		
Qty.transferred to *[Enter Title]*:			Total no. of shipper transferred:		
Approval: *(Only in case if the batch is to be discarded)*					
Approved by: *(QA Head)*			Approved by: *(Plant Head)*		
Name:			Name:		
Signature:			Signature:		

8. 231. Annex 2:Labels – Returned goods quarantine label

Returned Goods Quarantine Label	
Sales return no.:	
Product name:	
Batch no.	
Date of return:	
Net weight:	
Container no.:	
Signature:_____ Date: _____/_____/_____	

8. 231. Annex 3: Form - Returned goods log-book

Returned Goods Logbook						
Serial. no.:	Product name:	Batch no.:	Manufacturing no.:	Expiry date:	Hold month*	Date of receipt return:
Bulk material return from:	Return qty:	Proposed action:	Date of dispatch/reject:	Qty. dispatch/reject:	Closure:	Remarks:

14.3. SOP 337- Product recall procedure

Logo	**Standard format for SOP**: Product Recalls Department: _____ Policy No: _____

Company header: _____

Policy: _____

Handling of product recalls

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To establish the procedure for prompt and efficient recall of products known or suspected to be defective, from the market.

Scope:

This SOP applies to all types of recalls either initiated by XXX company voluntarily or by the National Regulatory Authority.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The designated responsible person shall ensure that product recall can be executed effectively and promptly upon receiving the recall instruction from the Managing Director or recall order from any Regulatory Authority.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Recall can be initiated in the following situations:
   - 1.1. A recall instruction decision from the Managing Director in response to a complaint received, where a serious product quality problem was detected in the product and/or product was found to have caused adverse reactions in consumers;
     - 1.1.1. A recall instruction decision from the Managing Director in response to any in-house detected defective products;
     - 1.1.2. A recall order from any Regulatory Authority. In this case the designated/responsible person shall consult the Regulatory Authority and Management to determine the extent and nature of the recall.
   - 1.2. Recalls are classified into the following categories:

Class 1 Recall

Initiated when the product defect poses a life-threatening situation to users. Some examples of defects that will result in Class 1 recalls are contamination with toxic substances and products with major labelling errors.

Such recalls shall be accorded the highest urgency and reported to NRAs (National Regulatory Authority and Overseas Regulatory Authorities where applicable) immediately.

Class 2 Recall

Initiated when the problem or defect is unlikely to cause serious harm to users. Some examples of defects that will result in Class 2 recall include products with minor labelling errors or products which fail to meet product specifications or pharmacopoeia standards (product liability for pharmaceutical articles) but are likely to cause a minimal hazard to users.

1.3. The designated responsible person shall inform the sales/marketing department or inventory control section to generate the distribution records of the affected batch.

1.4. All sales of defective products will be ceased immediately and the designated responsible person shall instruct the storekeeper to immediately remove any stock of the affected batch from the warehouse and quarantine the goods at the designated quarantine area.

1.5. All recipients of the affected product shall be notified of the nature of the recall by telephone. For end-user recall, appropriate mass media communication should be considered.

1.6. A recall letter will be prepared by the designated responsible person to be sent to all recipients of the affected batch as listed in the distribution record, to inform them that the recall operation has been activated, and to stop selling and remove the affected product from the racks with immediate effect.

1.7. The National Regulatory Authority and the Overseas Regulatory Authorities to which the affected product batch was exported should be notified of the recall in situations 4.1.1 and 4.1.2. Report must be made to the Officer of the National Regulatory Authority within 24 hours from receipt of the defective reports.

1.8. The designated responsible person shall instruct the delivery personnel to collect the recalled product back from the market, the pharmacies, hospitals, distributors or any other outlets as stated in the distribution record.

1.9. All recalled goods collected from the market shall be clearly identified and stored in the designated secure area while awaiting management's decision or National Regulatory Authority's instruction on how to handle the situation.

1.10. The progress of the recall process shall be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.

1.11. The records should be filed in the Recall file kept by the Admin or QC Department.

1.12. Mock recalls should be carried out on a yearly basis to assess the effectiveness of the recall system. Any irregularities found in the system during the mock recall shall be addressed so that procedures are activated immediately and promptly during an actual recall.

Definitions:

Product recall: a procedure for removal of a product from the market or extraction from all links of distribution. A product is usually removed or withdrawn due to major quality defects or serious adverse responses reported, which could result in health risks to consumers.

Withdrawal: The extraction of a product from sale or use by reasons unrelated or not attributed to the quality and safety of the product, but for reason of withdrawal due to marketing strategy or for packaging reasons.

Recall for Product Correction: When a product is removed for rework purposes

References documents:

14.337.Annex 1: Form – Product Recall

14.337.Annex 2: Form – Product Release Form

8.5 Returns: SOP 231- Handling of returned goods

14.337. Annex 1: Form – Product recall

Product Recall Record Form	
Form no.:	Revision no.:
Recall no.:	
Product particulars	
Name of product to be recalled:	
Strength of product:	Dosage form:
Pack size:	Batch number:
Date of manufacture:	Expiry date:
Quantity manufactured and released for distribution:	
Name and address of manufacturer:	
Country of manufacture:	
Date of recall:	Date of completion of recall:
Details of product defect	
Date of occurrence of defect:	
Nature of defect:	
Cause of defect:	
Number of occurrences of similar defects:	
Results of test or investigations:	
Assessment of whether recall is likely to affect other batches if same product(s) or other products manufactured by same plant:	
Class and level of recall:	
Proposed corrective action (if any):	
Reconciliation of product recall	
1. Quantity manufactured:	
2. Quantity sold/supplied in [country/town] attach copy of sales/distribution records:	
3. Quantity exported (attach copy of distribution records):	
4. Quantity of remaining stock in the warehouse:	
5. Total quantity recovered from recall:	
6. Quantity that cannot be recalled:	
7. Action taken on recalled stock (attach proof of action taken):	
Evaluation of recall: (whether recall is complete, explanation on any discrepancy):	
Follow-up actions taken:	
Name of person in charge of recall:	
Signature:	Date:

14.337. Annex 2: Form – Product release form

Product release form			
The following product is available for release to the market			
Product:			
Batch no.		Batch size:	
Mfg. date:		Expiry date:	
Packing details:		Number of intact:	
Loose pack:		Number of loose packed:	
Total qty. released		Total number of packed released:	
Quality control number:		Date:	
Reference number:			
Prepared by:		Checked by:	
Released by:		Format number:	

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 7: Production

Standard:	ISO EN 22716: 2007 COSMETICS GMP
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Chapter 7 Production

Introduction

In the GMP standard, production is defined as all processes involved in the manufacture of finished products, starting from processing to packaging. An inspector for the GMP standard will usually focus on the documentation and records on processing, transfer, formulations, in-process control methods and filling instructions. By implementing a detailed system where each process is outlined, the risk of mix-up and cross contamination can be greatly reduced. Hence should a mix-up occur with a particular batch, it should be possible to track down the batch. Thus, a good in-process control system creates production efficiency and product quality. This chapter draws attention to the importance of sampling throughout the production process of each product. To ensure that quality standards remain consistent, products will need to be tested after the completion of each stage of production before moving to the next stage. This will enable the production line supervisor to identify where a fault in the production process may have occurred, thereby improving the overall production rate and saving on unnecessary expenses. Authorisation by assigned personnel during each stage means that the product is constantly being monitored and scrutinised for potential threats.

Principle

To eliminate contamination during production, one should avoid working on more than one product sample simultaneously. To ensure product traceability, a track system should be introduced where all work procedures are recorded on paper, relatively authorised, thereby maintaining batch manufacturing records.

Scope

This chapter covers all activities involved in production. This includes starting materials (receiving, recording and sampling), the formulation of production documents, as well as the master formula, weighing activities, bulk production activities and all procedures involved with filling and packing. The scope of this chapter also covers aspects such as correct record keeping of each activity, which in turn is used to facilitate the traceability of finished products, quarantine, release to warehouse and reprocessing where applicable.

Purpose

The goal of GMP compliance within production for cosmetics is to ensure that the manufactured products are safe and of good efficacies and to promote the consistency of the quality of the product by inculcating the use of approved starting materials. Additionally, the aim is to create an approved standard for all processes and systems related to production activities. These activities should not only facilitate product follow-up, but it should also enable traceability. More importantly, the development of these systems and documentation thereof will allow the manufacturer to avoid cross-contamination, microbial contamination and errors in production.

Bulk production procedures

The cosmetic manufacturer must have relevant documentation available for every stage of the manufacturing operations. This documentation should include equipment, formula, batch numbers, quantities, procedures, temperatures, mixing times, sampling, cleaning, sanitising, transfer. Each manufactured product should have a written master formula, batch manufacturing record (BMR) and a quality control record.

Start up checks

The cosmetic manufacturer should ensure that proper documentation is available for all areas of production. The records should reflect that there is an adequate supply of raw materials available. Products and raw materials used in production must correspond to appropriate release forms. In addition to that, the appointed production supervisor should ensure that the correct procedure is followed with regards to the sanitation and maintenance of the equipment and machinery. The machinery used for a particular procedure should be suitable for the process and the area should be cleared, cleaned and sanitised from residues of the previous batch.

Before starting production activities, check the following:

- Line-clearance

Steps should be taken to ensure that:

- The work area, production lines, packaging lines, printing machines and other equipment are clear and free from any products, materials or documents previously used, if these are not required for the current operation.
- These should be performed according to an appropriate checklist.

Assignment of batch number

Another requirement for the GMP standard is the assignment of a batch number to each product lot. It is not necessary to assign a batch number to the final lot. This is to promote the traceability of each batch should any faults be found with a certain batch.

Identification of in-process operations

The GMP requirement of in-process operations consists of document procedures that detail the steps of all pn-process operations. Raw materials should be weighed and stored in labelled containers. The major equipment should be placed in containers that can be easily identified. That includes an indication of name, code, batch number and additional critical storage information.

In-process control

As already mentioned, many operations are involved during the manufacturing of a finished product and it is understood that quality is the responsibility of all the persons involved in the manufacturing process. Quality cannot be tested into products; it should be built-in (i.e. by design) and verified during the process to the highest extent possible rather than to depend on end product testing alone. Hence, it is necessary to check and control the critical points of the product during the manufacturing and up to the final packing of the product. Thus, the main purposes of In-Process Quality Control checks (IPQC) is

to monitor control and effectiveness of the complete applied operations at every stage of the finished pharmaceutical product. In-Process control includes inspection of raw material, equipment, environment, process, testing with respect to specification, packing and so on. The In-Process control is performed at regular intervals of either one hour or half an hour. Following the Good Manufacturing Practices eliminates the risks at every stage of the manufacturing process. Good Documentation Practices and Good Review Practices should be followed during the In-process checks to maintain the record.

Bulk product storage

The bulk product should be stored in containers that are compatible to the storage requirement of the type of product under it's ideal condition. The product label should have the maximum bulk storage duration printed on it. Once the maximum bulk storage duration has expired, the product goes through re-evaluation before use. Unused raw materials may be restocked in closed, labelled containers.

Packing operations

Packing is part of the production cycle starting from bulk product to the finished product. The key considerations of this section are that the operations should be conducted in accordance with an established In-process control (IPC) programme. The Out-Of-Specification (OOS) should be reported and investigated. The main idea is that a properly documented system should be in place and continuously updated to promote traceability and minimise mix-ups during production. The packaging line should be closely monitored, and all products and raw materials should be identified by proper labelling and documentation. If the process of filling and labelling is conducted at separate intervals, mix-ups or mislabelling should be avoided.

Checklist: Chapter 7 Production

Chapter 7 Production							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	7.1	**Principle**					
	7.2	**Bulk Production Procedures**					
	7.2.1	**Availability of Relevant Documents**					
158	7.2.1.1	Is each stage of the bulk manufacturing operation documented in the production record?					
	7.2.1.2	**Does the manufacturing documentation include:**					
159	7.2.1.2a	- the equipment / plant used?					
160	7.2.1.2b	- the formula?					
161	7.2.1.2c	- the list of all raw materials (including batch number and quantities)?					
162	7.2.1.2d	- detailed manufacturing operations for each stage (eg addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning / sanitisation, bulk product transfer)?					
	7.2.2	**Start Up Checks**					
163	7.2.2a	Is all documentation relevant to the manufacturing operations available?					
164	7.2.2b	Are all raw materials available and released?					
165	7.2.2.c	Is the equipment in working order?					
166	7.2.2.c	Is the equipment cleaned and, if necessary, sanitised?					
167	7.2.2.d	Is the production area free from materials from previous operations ("line clearance")?					
		Are sufficient exhaust systems for operations involving dust development:					
168		- Available?					
169		- Sufficiently dimensioned?					
170		- Correctly positioned?					
171		- In working order?					
	7.2.3	**Assignment of a Batch Number**					
172	7.2.3a	Does every batch of bulk product (e.g. filling product) have a batch number?					
173	7.2.3b	Can the batch number of a bulk product be easily assigned to the batch number of the finished product?					
	7.2.4	**Identification of In-Process Operations**					
174	7.2.4.1	Are all materials measured / weighed in accordance with the formula?					
175	7.2.4.1	Are all measured / weighed raw materials filled into clean and suitable containers labelled with appropriate identification and / or directly into the					

Chapter 7 Production							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
		equipment used for bulk manufacturing?					
176	7.2.4.2	Is an identification of equipment and containers of raw materials possible at all times?					
177	7.2.4.2	Is an identification of the main equipment and the containers with the bulk products possible?					
	7.2.4.3	**Does the identification of containers of bulk products include:**					
178*	7.2.4.3a	- name or identifying code?					
179	7.2.4.3b	- batch number?					
180	7.2.4.3c	- storage conditions (if important for product quality)?					
	7.2.5	**In-Process Control**					
181	7.2.5.1a	Have in-process controls with their acceptance criteria been defined?					
182	7.2.5.1b	Are the conduct of the in- process controls and their results documented?					
183	7.2.5.2	Are the in-process controls performed according to a defined programme?					
184	7.2.5.3	Are any results outside the acceptance criteria reported and appropriately investigated?					
	7.2.6	**Bulk Product Storage**					
185*	7.2.6.1	Are bulk products stored in suitable containers, in defined areas and under appropriate conditions?					
186	7.2.6.2	Has a maximum bulk product storage duration been defined?					
187	7.2.6.3	Is there a defined procedure if this duration is exceeded ?					
	7.2.7	**Re-stocking of Raw Materials**					
188	7.2.7	Are residual amounts of raw materials stored in closed and suitably identified containers?					
	7.3	**Packing Operations**					
	7.3.1	**Availability of Relevant Documents**					
189	7.3.1.1	Is each stage of packaging operations documented in the manufacturing record?					
	7.3.1.2	**Does the packaging documentation include:**					
190	7.3.1.2a	- the equipment / plant used?					
191	7.3.1.2b	- the list of packaging materials?					
192	7.3.1.2c	- a list of detailed packaging operations (filling, closing, labelling, coding)?					
	7.3.2	**Start-Up Checks**					

Chapter 7 Production							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
193	7.3.2a	Before starting any packaging operation is the area cleared of materials from previous operations ("line clearance")?					
194	7.3.2b	Are all relevant documents available?					
195	7.3.2c	Are all packaging materials available and released?					
196	7.3.2d	Is the equipment in working order?					
197	7.3.2d	Is the equipment cleaned and, if necessary, sanitised?					
198	7.3.2e	Is any coding available to permit identification of the product?					
		Are appropriate exhaust systems for operations with dust formation:					
		Are appropriate exhaust systems for operations with dust formation:					
199		- Available?					
200		- Sufficiently dimensioned?					
201		- Correctly positioned?					
202		- In working order?					
	7.3.3	**Assignment of a Batch Number**					
203	7.3.3.1	Does each unit of finished product have a batch number?					
204*	7.3.3.2	Is it easy to relate the batch of the bulk product to the finished product batch? (traceability?)					
	7.3.4	**Packing Line Identification**					
205	7.3.4	Is it possible to identify the packaging line with the finished product and it's batch number?					
	7.3.5	**Checks of Online Control Equipment**					
206	7.3.5	Is online control equipment, if used, regularly checked according to a defined programme?					
	7.3.5	**Checks of Online Control Equipment**					
206	7.3.5	Is online control equipment, if used, regularly checked according to a defined programme?					
	7.3.6	**In-Process Control**					
207	7.3.6.1a	Have in-process controls and their acceptance criteria been defined during packaging?					
208	7.3.6.1b	Are the performance of the in-process controls and their results documented?					
209	7.3.6.2	Are in-process controls performed according to a defined programme?					
210	7.3.6.3	Are any results outside the acceptance criteria reported and appropriately investigated?					

Chapter 7 Production							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	7.3.7	**Re-Stocking of Packaging Materials**					
211	7.3.7	Are residual amounts of packaging materials stored in closed and properly identified containers ?					
	7.3.8	**Identification and Handling of Work-in-Process**					
212	7.3.8	Is mix-up or mislabelling excluded if the processes of filling and labelling is carried out during separate periods of time ?					

7.2.4.178: Annex 1- Equipment Status Label

Cleaning Status of Equipment			
Company Name:			
Equipment Status:	CLEANED		
Checked by:		Date:	
Verified by:		Date:	
Valid until:			

Cleaning Status of Equipment			
Company Name:			
Equipment Status:	SANITISED		
Checked by:		Date:	
Verified by:		Date:	
Valid until:			

SMEs can also only use a pemanent marker to label the containers.

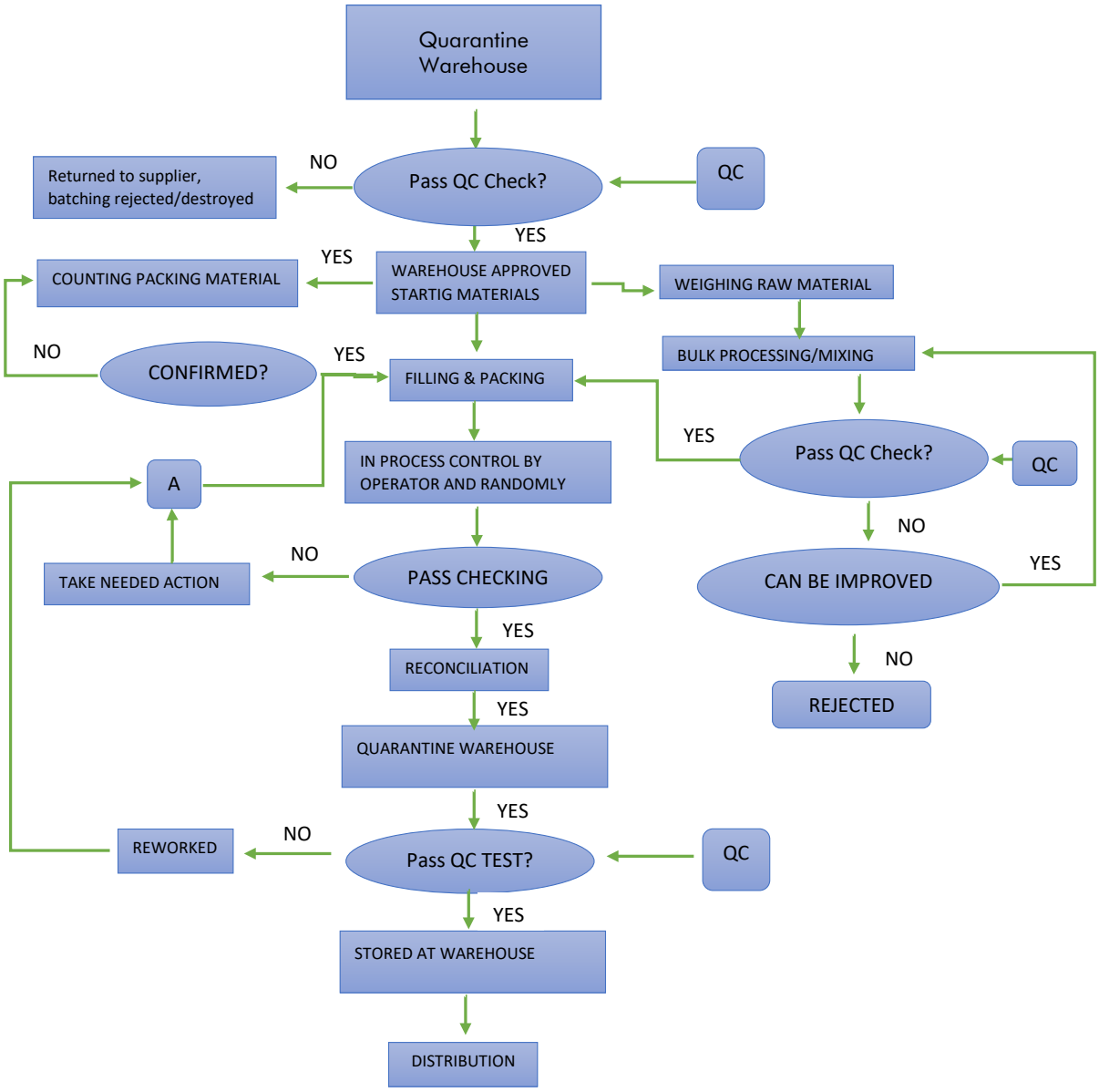
7.2.4. 178: Annex 2 - Bulk Quarantine Label

Cleaning Status of Equipment		
Company Name:		
Equipment Status:	QUARANTINE LABEL	
Formula Number:		Product Name:
Manufacturing Number:		Batch Size:
Processing Date:		Transfer Date and Time:
Bulk transferred to:		Bulk valid until:
Chemical:		
Microbiological:		
Sample finished Product:		

Colour code: Green (cleaned), Blue (sanitised), Red (quarantine).

Sample for in-process control SOP can be found at:
https://www.academia.edu/36130643/SOP_PRODUCTION_of_Cosmetics_according_to_ISO_22716_and_FDA_Guidelines

7.2.5. Annex 1: Flowchart – In-process control procedure



7.2.6. SOP 185- Reception, storage and delivery of starting materials

Logo	**Standard format for SOP:** Reception, storage and delivery of starting material Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To comply with the GMP requirement, starting materials used in production must be accompanied by requisition paperwork and that there is a cross-check that infomation matches the documented request before issued.

Scope:

This SOP covers all starting materials and includes raw materials, components and packaging materials which are to be received, logged, stored and delivered by [company name]

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Carrying out of task: Technical Assistant

Checking: Executive/Manager

Material and Equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Receipt of materials

1.1. Incoming materials must be examined visually to:

- Check that the container lid is intact and sealed correctly.
- Check for any visible damages or impairment to the container.
- Look for any evidence of insect or rodent contamination.
- The container should have correct labelling suitable to the contents.

1.2. Key information must be recorded and confirmed:

- Date of receipt
- Product title,batch number, control number, assigned by manufacturer.
- Check that the quantity received correlates with the quantity written in the document.

- The name of the supplier should be recorded.
- The purchase order number.

2. Storage of materials
   - 2.1. Clean the container externally, after receiving and before storage.
   - 2.2. Make sure to verify the quantity before storage.
   - 2.3. Store the material in the assigned area as per specified condition (low humidity area, cool dry place).
   - 2.4. The material should be stored according to the quarantine status (received, sampled, approved, rejected)
3. Delivery/dispatch of materials

   Goods must be double checked against documentation to verify:

   - Authorisation on the requisition.
   - The materials have the correct "released" status.
   - The item name and code are printed or stamped on the box.
   - Check the condition of the container; it should not be damaged or open.
   - Check that the dispatch order is within the expiry date of the material.

   3.1. Preparation for dispatch

   - The warehouse team must be notified by dispatch order, specifying the quantity and size of the batch.
   - The batch order should always be cross checked against the batch details.
   - If any batch is still in quarantine storage area, the supervisor should first be notified before any action.
   - Appropriate measures must be taken to protect the order from transport damage (e.g. extra outer packaging, labelling of transport temperature conditions, handling conditions, plastic wrapping around the container for an extra seal).
   - Ensure that the oldest material is dispatched first in accordance to "First in - First Out" (FIFO) system.
   - Maintain the appropriate dispatch records to ensure that each batch can be recalled if required.

   3.2. Preparation for transport

   - The release must be authorised by the QA before the finished batch is removed from quarantine.
   - Once released from quarantine, the batch label is completed according to status.

Reference documents:

8.3.1. Annex 1 - Sample of master formula

[Name of Company] Master formula							
Product name:				**Product Code:**			
Issue Date:				**Name Of Originator:**			
Ingredients	**Manufacturer**	**Lot#**	**Man. Expiry Date**	**Formula Quantity**	**Quantity Used**	**MFG by**	**Check by**

List of raw materials used:	**List of equipment used:**
Starting materials:	
Packaging materials:	

Manufacturer directions [procedure]
1.
2.
3.
4.
5.
6.
In-process controls and limitations:

Storage conditions:	
Components:	
Assembly method of finished products:	
History:	
Authorised by:	Signature:

8.3.1. Batch manufacturing record

Title:	Batch Manufacturing Record		
Product:	Revision no.		BMR no.
Batch no.:	Effective date:		Page no.
Specification of raw material:			
Serial no.	Ingredients	Specification	
1			
2			
3			
4			
5			
6			
Specification of labelling and packaging material:			
Serial no.:	Name of item	Specification	
1			
2			
3			
4			
5			
6			
Weighinment sheet:			
Serial no.	Ingredients (in order of mixing)	Specification	Labelled claim per dosage unit
1			
2			
3			
4			
5			
6			
List of equipment:			
1			
2			
3			
4			
5			
6			
Cleaning of equipment:			
Mixing:			
Equipment used:			
Date completed	Time completed	Duration of mixing	

Result of content uniformity attach analyses report)			
No. of containers			
Avg.Wt of sample found	mg	(A) Theoretical batch size	kg
IPQC Qty.	Nos	(B) Actual batch size	kg
Q.C. Analysis Qty.	Nos	(C) IPQC test qty.	kg
		(D) Q.C. Analysis qty.	kg
Expected yield		(E) Actual yield-	%
Reason for variation:			
Checked by - Production Chemist:			
QA Chemist:			
Coated started on: Coating completed on:			
Checked by Production Head:			
Reviewed by QA:			
Prepared by:	Checked by:	Authorised by:	Approved by:
QA Officer	Product Manager	QA Manager	GM QA/QC

Laboratory results

Processing work order (PWO)	Date of PWD released	Due Date	PWO document checked by (Production Manager)
	Filled by warehouse		
	Date of received PWO		
	Date of PWO delivery		

Product Code: Formula No : Product Name : Batch No.: Item :

Material code	Material Name	Analysis No.	Unit	Amount	Signature			Additional		Returned		Total used	Processing Date
				Nominal	Delivery	Warehouse	Production	Document	Amount	Document	Amount		
												Start	Finish
												(Processing SPV)	
												Acknowledged by (Production Manager)	
												Approved By (QC Manager)	

Record of using machine and man power

Machine code	Machine name	Machine				Man power process	
		STD	ACT			STD	ACT
			Operator	Washing	Total		
	Total:						

a. Theoretical Yield: kg	
b. Actual Yield: kg	
c. Actual Output (b/a X 100%) %	
d. Standard Output %	
Delivery Note No.	Remarks:

Packaging order

Company name: Packaging order	No. of packaging order:	Due date:	Printed and checked by: (Production Manager)
	No. of processing order		
	Date of packinging order:		
	Filled by warehouse		
	Date of received document:		
	Date of delivery:		

Product Code:	Formula:	Product Name:	Batch No:
Item:	Batch Size:		

PM code	Name of PM	Qc no /PWO no.	Unit	Amount needed		Signature		Additional		Damage		Return to WH		Total used	Note
				Standard	Actual	WH	Prod	Doc. No	Amount	Good	Damage	Doc no.	Amount		

Record of machines used and man power

Machine code	Machine name	Machine		Man power		Date	Total ouput		Delivery note	Remark
		STD	ACT	STD	ACT		Boxes	Pieces		

Result				Packaging date:		Checked by:	Approved by:
				Start	Finish		
a. Theoretical yield	pcs	e. Delivered to warehouse	pcs				
b. Actual yield	pcs	f. QC Sample	pcs				
c. Standard output	%	g. Sampling by other	pcs			(Production Manager)	(QC Manager)
d. Actual Output (b/a x 100 %)	%	h. Real yield (b-e-f-g)	pcs	Packaging SPV			

Processing instruction sample

Formula card No:	**Master Formula** Product name (powder) (sample)	Page:
Issued date:		Mixing date:
Issued by:		Batch no:
		Batch size:

Precautions and safety directions

1. Awarenees of handling and weighing of raw materials.
2. Operators need to wear suitable protective equipment.
3. Raw materials must not be ingested.
4. The weighing process must be carried out by at least two operators.
5. All of the pre-weighed raw materials should have a control number.
6. Pre-weighed raw materials must be separated.

Equipment

1. Mixer
2. Stainless steel beaker 5L
3. Filter
4. Storage tank

Equipment cleanliness

1.) Mixer No.: _____ Cleaning date: _____ Consecutive use:

SOP for cleaning: _____

Cleaned by: _____ Checked by: _____

Previous product: _____ Batch no.: _____

2.) Filter No.: _____ Cleaning date: _____ Consecutive use:

SOP for cleaning: _____

Cleaned by: _____ Checked by: _____

Previous product: _____ Batch no.: _____

3.) Storage tank no.: _____ Cleaning date: _____ Consecutive used:

SOP for cleaning: _____

Cleaned by: _____ Checked by: _____

Previous product: _____ Batch no.: _____

Line clearance	Operated by:	Checked by:
1. None of the opened raw materials are in the production area.		
2. Mixing tank, premix tank and other equipment is cleaned.		
3. All raw materials are approved.		

Remark: Any deviations from the Bulk Product Manufacturing Record should be checked by the Product Supervisor and recorded.

Comment :_____

Production Manager: _____ Date: _____

Prepared by:	Date:	Checked by:
Approved by:	Date:	
Reviewed by:	Date:	
Batch approval:	Date:	

Daily packaging report

Daily Packaging Report							
Part I: (line clearance)							
Date:	Room No.	Filling M/C:		Line Leader			
Previous product filled:			Lot No/Mfg date:				
Line leader checked and signed:							
Item checked:	Checked by:	QC inspection:	Filling equipment cleaning:	Remark:			
Bottle/cap bin			☐ First Operation				
Tub/jar/bottle			☐ Continuous filling				
Plug/cap			Cleaned by……..				
Unit carton			Sanitised by……..				
Sticker/label			QC Inspected by …….				
Shrink film							
Shipper							
Part II: Product filling							
Product name.:				Size:	_____gm/ml		
Lot No./Mfg date			Code:				
Code	Packaging component	Control no.	Qty from W/H	Damage from production	Defect from supplier	Qty returned	Checked by

Qty Produce = _____ Shipper Each Shipper contained _____ pcs. Total_____ pcc.(A) Q.C Sampling: _____pcs. (B)	Reported by:
Yield Reconciliation % Yield $= \frac{totalQtyproduct(A+B)}{theorecticalyield} x100$ = _____x100 = _____%	Checked report by:
Remark:	Authorised by:

If only one product batch is produced each day, it is easily possible to have the production record integrated into the BMR.

7.3.3. Assignment of a batch number: SOP – 204 Batch numbering and labelling system

Logo	**Standard format for SOP**: Quality of water used in production Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To introduce a labelling and batch numbering system that will fulfil GMP requirements for adequate labelling. The system should be clear, identifiable and facilitate the traceability of all cosmetic products and materials of [company name]

Scope:

This SOP provides instructions of a labelling system and batch numbering system that covers all requirements for all labels and product batches used in class 1 and class 2.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Control Department is responsible for the issuance of all Class 2 labels and shall ensure that Class 1 labels have met national regulations where applicable.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

4. Labelling system
   - 4.1. For production purposes, the cosmetic manufacturing company is required have a labelling system that can be used to identify the status of material, product, equipment, and laboratory reagents. This includes the labelling of demarcated and/or restricted areas within a cosmetic facility and includes warning labels.
   - 4.2. The labelling system is classified as follows:
     - Class 1 – labels for finished goods [insert label colour code].
     - Class 2- labels used within the factory to control progress [insert label colour code].
   - 4.3. Class 1 labels must meet the GMP 22176 standard regulatory authority requirements as indicated in the

marketing authorisation prior to use. In other words all finished product labels need to meet the national requirement.

4.4. Class 2 is used for internal labelling within the company. Class 2 labelling shall be overseen and regulated by the QC department.

4.5. The QC personnel shall be responsible for the issuance of status labelling based on the date and time the material/product/batch has been approved or rejected.

4.6. The cosmetic manufacturer shall assign a responsible individual from the QC or Production Department who signs the labels stating that equipment is available for use/cleaned or sanitised.

5. Class 2 labels indicating the status of a batch/product or material shall be colour coded as follows:

- Quarantine – [insert colour code]
- Accepted – [insert colour code]
- Rejected – [insert colour code]
- Cleaned – [insert colour code]
- Dirty – [insert colour code]

5.1. All labels should be clear and legible. The QC department shall be in charge of assigning labels for all containers, which includes but not exclusive to :

- Starting materials
- Intermediate materials
- Finished products
- Sample labels
- Sampled (already sampled)
- Process equipment
- Labels for all areas used for production (storage areas, quarantine areas, testing areas, etc.)

5.2. Class 2 labels include the following:

No.	Label Type:	Colour code	Reference Document
1.	Raw material tags	[insert colour code]	
2.	Quarantine status label release/rejected	[insert colour code]	
3.	Storage area identification labels	[insert colour code]	
4.	Biohazard / danger materials	[insert colour code]	
5.	Restricted access labels	[insert colour code]	
6.	Equipment	[insert colour code]	
7.	Restricted access labels	[insert colour code]	
8.	Equipment cleaned/waiting for cleaning labels	[insert colour code]	
9.	Process intermediate labels	[insert colour code]	
10.	Final product labels	[insert colour code]	

5.3. All raw materials/bulk materials and finished product labels should have a product number or identification code to enable it to be tracked and identified easily by production staff.

Definitions:

Reference documents:

8

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 8: Finished Products

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Revision No.:	00
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Chapter 8. Finished Products

Introduction

According to the GMP standard, a product may be considered a "finished product" once it has undergone all the stages of production, including packaging in its final container. The finished product may only be "released" into the market once it has been approved by QC officials and should remain in the quarantine area until such approval has been granted. The focus in this chapter is on finalisation of documentation, labelling and assurance of the safety of the product before it is marketed. According to GMP regulations a cosmetic product may be considered adulterated if it contains filth, it is harmful to the consumer under conditions of customary use due to the product content or, if the container was made of a potentially harmful substance. A cosmetic product may be considered adulterated if non-permitted/non-certified colour additives were used in the product and, if the manufacturing conditions were unsanitary or contamination occurred. A cosmetic product may be regarded as misbranded if the product label does not correspond with the contents i.e. it is false or misleading and if the container presentation and fill is misleading.

Principle

To fulfil the GMP requirements of finished goods. Finished goods should be kept under quarantine prior to release. It should be labelled with the date of packing, product name, batch number and quantity. The finished product shall only leave quarantine once the control has been completed and it has been inspected by the quality department. In special cases, a release of products, only to wholesalers, is possible before QC has been completed. However, transport to retailers is forbidden.

Scope

This chapter covers all considerations for GMP compliance related to finished products such as release, storage, shipment and returns. The cosmetic manufacturer should pay close attention to certain key elements: (a) released products should be authorised by staff; (b) products should be stored in dedicated storage areas; (c) all necessary information on containers should be documented; (d) the finished product should be released according to the "First In - First Out" principle; (e) any returns from the market should be evaluated according to a well-established system.

Release

Before the finished product can be released into the market, the products must be tested according to established procedures. The product must be compliant with the specified acceptance criteria of the cosmetic manufacturing company based on the GMP standard requirements. The finished product may only be released once it has been authorised by quality control.

Storage

Once released from quarantine, the product should be stored in a suitable storage area that agrees with the conditions and time requirements of the product. The cosmetic manufacturing facility should have clearly demarcated areas for released, quarantined, or rejected products. The finished product should be stored according to the relevant label on the packaging (released, quarantined, rejected). The containers are labelled indicating the name, code, batch number, storage conditions and quantity. The company could implement

Good Storage Practice (GSP). This will ensure that the finished product is of good quality and safe before it reaches the consumer. There are five key components to consider when implementing GSP:

- premises or warehouse
- personnel, storage facilities
- stock management and control
- documentation.

Shipment

Before any finished product may leave the manufacturing plant, it must be authorised and checked by Quality Control personnel. The manufacturer should ensure that appropriate precautions were taken to maintain the quality of the finished product during transportation.

Returns

The cosmetic manufacturer should ensure that there is an established system in place with regards to the handling of returned goods. The returned goods should be labelled respectively and stored in a defined area. Upon return, the product should be evaluated against the established criteria for additional dispositions. Once the product has gone through the full process and the correct documentation has been completed, the product may be authorised for release before re-marketing.

Checklist: Chapter 8 Finished products

Chapter 8 Finished products							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	8.1	**Principle**					
	8.2	**Release**					
213 *	Calibration Act / ISO 2859-1	Are there any binding specifications including acceptance criteria?					
214 *	8.2.1.a	Are finished products controlled in accordance with established test methods prior to being placed on the market?					
215	8.2.1b	Do the finished products comply with the acceptance criteria prior to being placed on the market?					
216	8.2.2a	Is the product release carried out by the authorised personnel responsible for quality?					
217	8.2.2b	Is the product release adequately documented?					
	8.3	**Storage**					
218 *	8.3.1	Are the finished products stored in defined areas under appropriate (if necessary, monitored) conditions and for an identified length of time?					
219	8.3.2	Are the storage areas equipped and organised for this purpose?					
220	8.3.3	Are finished products which are released, quarantined or rejected, stored in their respective physical locations or is a data system available which ensures segregation?					
	8.3.4	**Are the containers with the finished products (shipment unit and / or pallet) identified with:**					
221	8.3.4a	▪ name or identifying code (material number)?					
222	8.3.4b	▪ batch number?					
223	8.3.4c	▪ storage conditions (if necessary for product quality)?					
224	8.3.4d	▪ quantity?					
225	8.3.5	Is the finished product with the oldest release date used first (FIFO principle)?					
226	8.3.6a	Are periodic inventory checks carried out?					
227	8.3.6b	Are the quantities recorded by quality status?					
228	8.3.6c	Is every significant discrepancy investigated after the inventory?					
	8.4	**Shipment**					

Chapter 8 Finished products							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
229	8.4a	Are there any measures which ensure the shipment of the defined finished product?					
230	8.4b	Have precautions been taken to maintain the finished product quality?					
	8.5	**Returns**					
231	8.5.1	Are returns identified and stored in defined areas?					
232	8.5.2	Are returns evaluated against established criteria?					
233	8.5.3	Are returns released again before they are placed back on the market?					
234	8.5.4a	Is it possible to clearly identify reprocessed returns?					
235*	8.5.4b	Is an inadvertent redistribution of unreleased, returned finished products excluded?					

References: IKW Cosmetics GMP based on ISO 22716

Reference Websites:

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

National Pharmaceutical Regulatory Division Ministry Of Health Malaysia: Guideline On Good Distribution Practice: https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/2018/GUIDELINE_ON_GDP_3rd_Edi_2018.pdf

Cosmo Sourcing: How To Make A Product Specification Sheet For Your Fba Product // Step-By-Step Guide: https://www.cosmosourcing.com/blog/how-to-create-a-great-product-specification-sheet

Big Rocks Engineering: Product Development: Starting The Product

Specification: https://hillsinnovativesolutions.com/product-development-specification/

8.2. Release - 213 SOP for Acceptance criteria and specification of starting material, process water, in-process bulk/product, and finished product.

Logo	**Standard format for SOP:** Acceptance Criteria and specification of starting material, process water, in-process bulk/product and finished product Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective Date: _____ Replaces: _____

Purpose:

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Quality Assurance Manager

Quality Control Department – shall approve, sign, date and maintain each specification

Accountability:

Materials and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Starting Material Specification
    1.1. The QA manager draws up a specification for starting materials including the following:
        1.1.1. Designated name
        1.1.2. Internal Code
        1.1.3. Reference (where applicable)
    1.2. The specification must include the quantitative and qualitative requirements along with acceptance limits.
    1.3. Based on the company practice, the following data is added to the specification:
        1.3.1. Name of supplier

1.3.2. Name of original producer
1.3.3. Storage requirements including conditions and precautions
1.3.4. The maximum period of storage before re-examination

2. Starting Material Acceptance
   2.1. Prior to use, the QA manager ensures that all starting materials are verified.
   2.2. The QA manager ensures that the verification includes a review of the Certificate of Analysis from the manufacturer compared with the approved specification.
   2.3. Where necessary, the QA manager conducts an identification test and other examinations on the characteristics of the material.
   2.4. Primary packaging should be examined for leaks, sharp dents, tears, exposed parts and seal integrity.
   2.5. The QA manager conducts checks to ensure that the packaging label, batch number and identification numbers are clear and correct.
   2.6. The QA manager shall allocate the frequency of tests and checks for each manufactured batch.
3. Process Water Specification
   3.1. The standard for drinking water shall be defined as the "minimum standard" for use in cosmetic processing.
   3.2. QA ensures that the specification for microbial and chemical quality are based on the point or purpose of use.
   3.3. Based on the requirement, the QA ensures that water quality tests are conducted on a weekly/monthly basis.
   3.4. Depending on product formula, process and claim requirement, further treatment may need to be implemented. In the case of further treatment, the QA manager must base the specification for water on the supplier design specification or the pharmacopoeia standard.
   3.5. The cosmetic manufacturer must carefully review the quality of water to be used, particularly where water comprises most of the product content. This is important because, in many cases, water is the fundamental raw material used in many cosmetic formulas. As a result, the choice of water quality will greatly impact the quality and stability of the final product.
   3.6. De-ionised water should be utilised for products which are intended for use near the eye area, mucus membrane and oral cavity as well as for products for babies.
4. Process Water Acceptance
   4.1. The cosmetic manufacturer must ensure that water quality meets national or WHO drinking water standards.
   4.2. The QA shall ensure that the treated water specification is established based on supplier's design specification or the pharmacopoeia standard.
5. Finished Product Specification
   5.1. The QA manager shall include the following in the product specification document:
      5.1.1. Designated name
      5.1.2. Internal code
      5.1.3. References (where applicable)
      5.1.4. Formula number
      5.1.5. Shelf life (where applicable)
      5.1.6. Batch numbering requirement (including manufacturing date or expiry date)
   5.2. The QA manager shall include a description of the finished product and the relevant packaging information in the product specification.
   5.3. The finished product specification shall also include the qualitative and quantitative requirements with acceptance limits.
   5.4. The QA shall also ensure that the finished product specifications include instructions for product sampling and testing or at the very least provide reference to an approved procedure.
6. Finished Product Acceptance

6.1. The owner must conduct a review of the batch manufacturing record.
6.2. The QA manager must conduct a review of all non-conformance or deviation documentation on the Batch Manufacturing Record (BMR) and corresponding rework/reprocessing instruction.

7. In-process control
   7.1. The owner shall conduct periodic tests at specified sampling intervals based on process monitoring and actual sample testing. Regular inspections should be done with respect to the aforementioned attributes.
   7.2. The results from the abovementioned inspection and testing shall be attached to the BMR.
   7.3. The QA manager must ensure that the abovementioned process is in agreement with the BMR requirements and packaging record requirements.
   7.4. Where necessary, the owner may make use of control charts and other statistical tools for process capability to illustrate trend analysis.
8. In-process Bulk/ Product Acceptance
   8.1. The owner shall conduct in-process inspection and testing through monitoring the process or via sampling analysis at specified locations and specified times.
   8.2. The owner ensures that the results comply with the process parameters or acceptable tolerances.
   8.3. The owner shall ensure that all packaging lines follow line clearance.
   8.4. Where applicable, the QA manager shall ensure that a standard reference for labelling, coding and format requirement is available to packing staff.

Definitions:

QA – Quality Assurance

WHO – World Health Organisation

BMR – Batch Manufacturing Record

References documents:

8.213. Annex 1: Form – Product Specification

8.213. Annex 2: Form – Product Specification Sheet

8.213. Annex 3: Form – Starting Material Specification Sheet

8.5. Returns – SOP 235: Finished Good Withdrawal/Retention

SOP for quality control in-process control

Special note for SMEs

It is useful to have specifications directly on the batch manufacturing record (BMR), to be checked/ticked off there. Since SMEs might not have QA managers, either the owner or the qualified staff member carrying out the production has to sign off on the specification of raw material.

8.213. Annex 1: Form – Product specification

Product Specification	
Product	
Dimension	
Material	
Target Price	
Initial Order Quantity	
Product Function	

8.213. Annex 2: Form – Product specification sheet

Product Specification Sheet		
Format no:		
Product ID	**Product specification no.**	**Product specification record sheet no.**
Product		
Product characteristics	**Specifications/characteristics descriptions**	
Standard reference		
Product/material composition		
Chemical compositions		
Biological (if applicable)		
General conditions		
Application/intended use		
Safety requirements		
Handling requirements		
Storage requirements		
Basic preparation requirements		
Usage requirements		
Method of storage/handling/distribution		
Legal/applicable acts and status or regulatory compliance		
Shelf life		
Prepared by:		Approved by:

Special note for SMEs: Integrate into BMR for ease of use

8.213. Annex 3: Form – Starting material specification sheet

Starting Material Specification Sheet		
Format no:		
Product ID	**Product specification no.**	**Product specification record sheet no.**
Product		

Product characteristics	**Specifications/characteristics descriptions**
Standard reference	
Product/material composition	
Chemical compositions	
Biological (if applicable)	
General conditions	
Application/intended use	
Safety requirements	
Handling requirements	
Storage requirements	
Basic preparation requirements	
Usage requirements	
Method of storage/handling/distribution	
Legal/applicable acts and status or regulatory compliance	
Shelf life	

Prepared by: Approved by:

Special note for SMEs: Integrate into BMR for ease of use

8.2. Release - SOP 214 for Sampling finished goods

Logo	**Standard format for SOP:** For Sampling Finished Goods Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title : _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose is to introduce the procedure for sampling of finished goods during the manufacturing process.

Scope:

This SOP shall be applicable to the Quality Control Department.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Assurance supervisor shall be responsible for the upkeep of this document.

Accountability:

Quality Assurance Manager/Head

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Preparation:
   - 1.1. Once the finished product has completed the final stage, the Batch Manufacturing Record must be completed and signed.
   - 1.2. Ensure that all appropriate manufacturing steps and procedures have been met and properly documented.
   - 1.3. The testing request form is then completed and handed over to the In-process Quality Assurance office for sampling.
   - 1.4. Ensure that the correct equipment for sampling (e.g., clean spatula, self-sealing polybags, labels, and sampling rod) have been set-up and available for use.

1.5. The “In-process sample” contains the product name, batch number, sampling quantity, production stage, test to be conducted, sampling date, sampled by and time of sample submission.

2. For lotions

2.1. The QA officer in charge shall be notified by the packing department of the start of the packing operations.

2.2. The QA officer shall pick up the sample from the packing line.

2.3. The quantity of the sample should be sufficient to conduct the sampling test at least twice.

2.4. The sampling test should be conducted according to the outlined procedure.

2.5. The sample shall be collected at the start, middle and final stages of packing operation.

Definitions:

References documents:

8.5. Returns – SOP 235: Finished Good Withdrawal/Retention

8.5 Returns: SOP 231- Handling of returned goods

8.5. Returns – SOP 235: Finished goods withdrawal/retention

Logo	**Standard format for SOP:** Finished goods withdrawal Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title : _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the procedure for withdrawal/retention of finished goods in cosmetic production.

Scope:

This SOP is applicable for withdrawal and retention of finished goods from production processes.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The QA department is responsible for withdrawal and retention of finished goods.

Accountability:

The head of QA shall be held accountable for compliance of this SOP.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Control sample shall be withdrawn from each batch of product manufactured.
   1.1. Quantity of sample shall be withdrawn in accordance with the table below:

Serial .no	Sample	Quantity of sample drawn (in unit)
1	Lotion	200
2	Cream	200
3	Essential oil	200

1.2. The QC staff collects the control samples in accordance to the table from each batch of finished goods throughout the packing procedure, and enters the information in the Product Control Logbook for samples.
1.3. For the retention of raw material samples, the QC staff must extrapolate the sample and record the information in the Raw Material Retention Logbook for samples.
1.4. The sample shall be labelled with the control sample sticker on each pack.
1.5. The Control sample should be a proportional representation of the variety of pack sizes of the same batch.
1.6. Solvent and liquid samples should not be kept in the control sample room.

2. Storage
   2.1. Storage temperature for control samples [25°C]
   2.2. the storage temperature should be monitored, maintained and recorded.
3. Physical analysis of the control sample
   3.1. Conduct the sample analysis every six months and record the results in the relevant file.
   3.2. The analysis should include (but not limited to) the following points:
      3.2.1. Description of physical appearance
      3.2.2. Quality of packing
      3.2.3. Imprinting
      3.2.4. Overprinting
      3.2.5. Integrity of packaging

Definitions:

References documents:

8.5 Returns: SOP 231- Handling of returned goods

8.3. Storage – SOP 218: Receiving, storage, and distribution of materials

Logo	**Standard format for SOP:** Receiving, storage, and distribution of materials Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Accountability:

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Receiving
    - 1.1. Each incoming delivery should be verified against the supporting documentation. The label description, quantity and variety should be physically checked against the corresponding purchase order. It also includes the certificate of analysis.
    - 1.2. The aforementioned certificate of analysis must originate from the approved suppliers.
    - 1.3. Upon receipt of each consignment, the packing staff check for uniformity and if necessary, it shall be separated according to the supplier's lot numbers if more than one batch has been delivered.
    - 1.4. Prior to storage or distribution, warehouse staff shall carefully inspect each container for damages, contamination or tampering. If the item is suspicious the container or entire consignment shall be sent to the appropriate quarantine area or placed separately for additional investigation.
    - 1.5. The Warehouse Manager ensures that the records for each delivery are retained.

1.6. Each delivery order shall be affixed with the following supporting information:

- Product Description
- Quality/Grade (if applicable)
- Quantity
- Supplier details
- Supplier Batch Number
- Date of receipt
- Date of assignment
- Batch number

1.7. Stored in final pack to ease carrying, reduce chances of spoilage and damage of the product.

1.8. Depending on current regulations the period for retention is the following:

1.8.1. Quarantined cosmetics or products shall not be removed from quarantined status until a release/rejected statement has been issued by the authorised personnel.

1.8.2. Any products with specified storage requirements, shall immediately be identified and stored including the written procedure.

2. Stock rotation and control

2.1. Stock reconciliation shall be conducted on a periodic basis and the physical product shall be verified against the recorded product or cosmetics quantity.

2.2. Any discrepancies found in the stock is checked against unintended mix-ups and wrong issues of stock.

2.3. All distributions or deliveries shall be issued by observing the (FIFO) "first in - first out" stock rotation protocol especially with products or cosmetics with expiry dates.

2.4. Sale and supply of products or cosmetics with compromised seals, impaired packaging or suspected contamination are strictly prohibited.

2.5. Each consignment shall be checked on a regular basis for expired products or cosmetics.

2.6. All necessary measures shall be taken in accordance with written procedures to prevent the issuance of expired products or cosmetics.

2.7. The tampering or changing of labels and containers of any products or cosmetics is strictly forbidden.

2.8. Acts and regulations relating to labels and containers should always be adhered to.

2.9. Products/cosmetics in cartons/bulk packs should be adequately labelled with at least the product name, batch number and expiry date or retest date.

2.10. Repacking (including relabelling) of products/cosmetics may be carried out only by the company which holds a license or approval from the authority unless activities are exempted from these requirements.

3. Returned and rejected

3.1. Warehouse staff shall ensure that all returned and rejected goods are retained in the quarantine area and shall be distinctly labelled or marked as such.

3.2. All returned and rejected goods shall be stored separately in a restricted area.

3.3. Any written risk-based procedure(s) shall be followed based on the product of concern. This includes details regarding specific storage requirements and the time which has elapsed since the product/cosmetic item was originally dispatched.

3.4. National legislation and contractual arrangements shall be honoured and adhered to in regard to handling returned goods.

3.5. The Warehouse Manager shall maintain and keep records of all returned goods.

3.6. The outcome of returned and rejected products/cosmetics is decided after a thorough examination by a qualified and competent person.

3.7. Returns and rejected products/cosmetics should be transported and stored in line with relevant warehousing procedures and other standards, in a safe and acceptable manner.

3.8. Products or cosmetics to be returned to saleable stock shall be placed in such a way that the stock rotation (FIFO) mechanism works effectively.

3.9. Stolen products or cosmetics that have been recovered cannot be restocked and resold to the public.

3.10. All action taken should be approved and recorded.

3.11. To avoid confusion, any counterfeit products/cosmetics discovered in the distribution network should be physically separated from other products/cosmetics. They should be labelled with the wording "Not for Sale" or similar. The regulatory authority and the holder of the original product's marketing authorisation should be notified right away.

3.12. The warehouse manager shall keep track of any returned products or cosmetics. The following items are included in the return documentation:

3.12.1. Name and address of the consignee returning the products or cosmetics.

3.12.2. Name or designation of products or cosmetics,

3.12.3. Batch number

3.12.4. Quantity returned

3.12.5. Reasons for return

3.12.6. Use or disposal of the returned products or cosmetics

3.12.7. record of the assessment performed

4. Distribution

4.1. To ensure that the correct product or cosmetic is chosen, controls should be in place. When the product is selected, it should still have a suitable shelf life.

4.2. Only after a sales order has been received may shipping materials be allocated. Depending on the nature of the products/cosmetics and any additional precautions that must be maintained, requirements for distribution methods should be defined.

4.3. The product should be tested before shipping if it has been stored for long.

4.4. The likely impact of shipping should be assessed and documented. This should include impact of delays during transportation or change in weather conditions such a temperature, pressure and humidity.

4.5. If products are affected by light for example, oxidation, opaque packaging materials should be considered.

4.6. Shipping documentation to show product, quantity, shipping conditions (duration, temperature, humidity), and special precautions for example, what to do in case of excessive delays or weather severe changes.

4.7. Import and export activities should be carried out in compliance with national laws and, if applicable, international guidelines or standards. This is also the case if wholesalers or importers are keeping products in a free trade zone. Wholesalers should take the necessary precautions to ensure that products or cosmetics that are not approved for the internal market and are intended for export do not enter the market.

4.8. Only wholesale dealers or anyone authorised to supply the products/cosmetics shall receive deliveries.

4.9. There should be a defined process for delivering products or cosmetics to end consumers.

4.10. A mechanism should be in place that allows the distribution of each batch of products or cosmetics to be easily identified so that it may be recalled.

4.11. For each supplier there should be a document such as a Delivery Order which includes the following:

4.11.1. date

4.11.2. name of products or cosmetics,

4.11.3. batch number,

4.11.4. quantity supplied,

4.11.5. name and address of supplier,

4.11.6. name and delivery address of the consignee (actual physical storage premise, if different)

4.11.7. applicable transport and storage conditions.

4.12. The warehouse manager shall keep and maintain the records to determine the exact place of delivery of products or cosmetics.

5. Disposal

5.1. Products/cosmetics that are destined for destruction should be properly identified, separated, and

handled according to written procedures.

5.2. Product/cosmetic destruction should be carried out in accordance with national legislation and regulatory standards and with adequate regard for the environment.

Definitions:

References documents:

8.5 Returns: SOP 231- Handling of returned goods

8.5. Returns: SOP 231- Handling of returned goods

Logo	**Standard format for SOP:** Returned Goods Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The objective of this SOP is to define the procedure for handling of returned goods, redressing and repacking.

Scope:

This procedure is applicable for redressing, handling and repacking of finished goods by reason of shelf-life extension, renewed price or price adjustment, and returned goods from any other location or retail.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

1. It is the responsibility of the Warehouse personnel:
   - 1.1. To notify the QA and production departments regarding receipt of finished goods.
   - 1.2. To maintain the records of returned goods.
   - 1.3. Check all documentation and the conditions of the returned goods.
   - 1.4. Ensure that the items are stored correctly in the identified areas in accordance with the recommended condition.
2. It is the responsibility of the QA personnel:
   - 2.1. To verify the physical status of returned goods and make sure that the introduction protocol is followed in accordance with SOP.
   - 2.2. To provide a batch packaging record where applicable to redressing or repacking of finished goods and returned goods.
   - 2.3. To withdraw the control sample.
   - 2.4. To ensure that the batch is released once all packing activities are done.
3. Quality Control personnel are responsible for the investigation of the returned goods as per recommendation by the QA Head.
4. Production personnel are responsible for:
   - 4.1. Establishing a packing plan as designed by the QA Head.

4.2. Provide a bill of material
4.3. Provide a work order
4.4. Maintenance repair operation, where applicable.

The Plant Head and Quality Head shall be responsible for the review and approval of the SOP and to ensure the compliance of this introductory procedure.

Accountability:

Materials and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Handling of returned goods
   1.1. Receipt and handling of returned goods:
      1.1.1. Upon arrival, all returned goods are received by the warehouse personnel.
      1.1.2. Materials are stored as per the storage conditions of the respective products, in the correct designated area for returned goods.
      1.1.3. The area is identifiable by label or marking.
   1.2. Warehouse personnel check and verify the consignment against the information on the receipt documents (Delivery Note or Order):
      1.2.1. Identity of the product / Validity of labels.
      1.2.2. Batch Code or Number.
      1.2.3. The number of Containers/Shippers received in comparison to the supply.
      1.2.4. Condition of Containers/Shipper's (intactness and seal integrity).
      1.2.5. Weight and the total quantity of returned Containers/Shippers.
   1.3. The physical state of the returned goods shall be carefully inspected by the warehouse official, and the details shall be written in the "Returned Goods Verification Report".
   1.4. Warehouse personnel are required to produce a "Distribution Receipt".
   1.5. After completing the "Distribution Receipt" and entering it into the system, and after physical verification of the returned goods, warehouse personnel send the "Returned Goods Verification Report" to the QA for verification.
   1.6. Each shipment/batch shall be verified by the QA, who will then make a recommendation/decision based on the following:
      1.6.1. If the material is returned by reason of commercial dispute or because of not meeting the physical specifications.
      1.6.2. If the material is found to be intact, and the seal number and label number correspond with the packing details, then management shall approve the release of the material for direct re-sale.
      1.6.3. If the material is returned by the customer by reason of commercial dispute or because the product does not meet the physical specifications. If the seal is broken by the customer, the material must be verified, and QA shall make a decision based on observation and as per the "Goods Verification Record".
      1.6.4. In the case where the material has been affirmed as contaminated or it is a case of sabotage, the material shall be sent for disposal or destruction according to the "Goods Verification Record".
   1.7. Once the physical verification of returned goods has been completed by warehouse personnel and QA:
      1.7.1. The warehouse shall be responsible for cleaning or redressing (in case of Shipper) of the returned goods in line with the required conditions.
      1.7.2. A "Returned Goods Quarantine label" shall be printed and attached to each container by the warehouse staff as per the recommendation from the Head of Production and Quality Assurance in the "Goods Verification Record".
      1.7.3. Note: Materials to be discarded are not required to have "Returned Goods Quarantine" labels.

1.7.3.1. The "Returned Goods Verification Record" is completed by QA staff and sent to the Head of QA and the Head of Production for further recommendation.

i. Based on the recommendation of the "Returned Goods Verification Report", returned goods are allowed for sampling and re-analysis as follows:

ii. If after re-analysis, the result is found to comply with the specification parameters, then the material shall be redressed/re-packed and released for re-sale.

iii. If the material does not comply the specification parameter, then it shall be discarded as per decision in the "Returned Goods Verification Record".

iv. Based on the recommendation of the Production Head and QA Head:

1) QA personnel shall forward the "Returned Goods Verification Report".

2) QC, in case it is recommended for sampling and reanalysis.

3) Packing, in case sampling and re-analysis are not required and material can be packed directly.

1.8. Warehouse storeroom in case material is recommended for disposal:

1.8.1. QC will produce a Quality Control Order in the system for sampling and retesting/re-evaluation if materials are recommended for re-analysis.

1.8.2. QC will complete the section in the "Return Goods Verification Report" and will perform the inspection and re-testing of the returned goods.

1.8.3. Once the reanalysis is complete, the material shall either be "Approved" or "Rejected" by the QC and all the accompanying documents as well as the analytical documents shall be sent to QA for further decision.

1.8.4. The QA shall thereafter send a recommendation for either "redressing" or "repacking" or "destruction", based on the results of the analytical data and findings of the material in accordance with the "Goods Verification Record".

1.8.5. In the event where retesting is not necessary during sampling of returned goods and redressing or repacking has been sanctioned directly, then the QA shall send the "Returned Goods Verification Record" directly to the packing department.

1.8.6. In case it is decided to reprocess the goods, then it shall be handled through the SOP of "Reprocessing" and the manufacturing and expiry date of goods shall remain unchanged.

1.9. Returned Products' final disposition must be concluded within 60 days of receipt.

1.9.1. Returned products that have been marked for disposal shall be disposed of according to the instruction in the "SOP for the handling of rejected materials" in the production sites.

2. Redressing of Returned Goods:

2.1. After receipt of the "Return Goods Verification Report" from the QA officials, the packing staff shall write up the "Redressing Record Request Form".

2.2. Prior to packing procedures, the packing staff collect the returned goods from the warehouse storage area and store them in a more suitable place.

2.3. After verification of the manufacturing date and expiry, the QA shall release and sign the Batch Redressing Record.

2.4. The QA issues the authorised batch redressing record after verifying the manufacturing and expiry dates.

2.5. The QA includes any required information in the same register as the previous entry.

2.6. The redressing procedure is initiated as soon as the packing official has received the Batch Redressing Record.

2.7. Packing personnel are responsible for the line clearance of area and equipment.

2.8. This is also recorded in Batch Redressing Record.

2.9. The packing officer and QA officer shall perform the in-process check during the redressing activity.

2.10. QA records this in the Batch Redressing Record.

2.11. After completion of the redressing activity, the QA officer withdraws the Control Sample and ensures complete documentation of the Batch Redressing Record.

2.12. After completion of the Batch Redressing Record, the QA officer completes the final inspection report. If

found satisfactory, the QA officer releases the batch for dispatch.

2.13. The QA officer checks for any discrepancy found during final product inspection, it shall be discussed with the QA Head and corrective action shall be taken as per the recommendation of the QA Head.

2.14. The QA checks and reviews the redressing record again and releases the batch.

3. Returned Goods Repacking:

3.1. Once (8. 231.Annex 1: Form) "Returned Goods Verification Record" has been received from the QA department:

3.1.1. The returned goods are retrieved from the warehouse storeroom by packing personnel

3.1.2. The returned goods are stored in a suitable place prior to the packing operation.

3.2. All re-packed finished goods receive a designated batch number and are annotated with the "R" symbol.

3.3. Once packed, packing staff must ensure that returned goods are placed in controlled areas.

3.4. The physical state of packaged goods is checked by packing staff and QA staff.

3.5. Based on the inspection and review of the bulk lot, the QA makes the final decision for the goods to be either packed or disposed.

3.6. Should the physical state of the returned goods be deemed faulty, it may be discarded in accordance with "8. 231.Annex 1: Form Returned Goods Verification Record".

3.7. Should the returned goods be deemed up to standard, then a "Batch Packing Record" shall be requested from the QA department by the packing staff.

3.8. If needed, the QA extracts a sample and dispatches it to the QC laboratory who, in turn, conduct an analysis along with the required report.

3.9. All returned goods shall be stored in the designated storage facility until they are ready for the packing process. The goods will then receive the required status label.

3.10. Packing staff make use of the Quarantine Inward/ Outward logbook should any bulk goods be transferred to the quarantine storage facility.

3.11. "A Batch Packing Record" shall be authorised and issued by the QA once the manufacturing date and expiry date have been confirmed.

3.12. The QA department shall ensure that the "Batch Packing Logbook" is updated with each new entry.

3.13. Upon obtaining the "Batch Packing Record" the packing staff initiate the repacking procedure.

3.14. Prior to commencement of the packing procedure, packing staff conduct the necessary line clearance and prepare equipment according to the appropriate SOPs.

3.15. The packing officer and QA officer perform the in-process check during the repacking activity.

3.16. The above is recorded in the Batch Packing Record.

3.17. After completion of the repacking activity QA ensures complete documentation in the Batch Packing Record and withdrawn Control Sample.

3.18. After completion of "231.Annex 1: Form Returned Goods Verification Record":

3.18.1. The analytical results are attached to the Batch Packing Record.

The warehouse personnel complete the "8.231. Annex 3: Form - Returned Goods Logbook"

Definitions:

Returned Goods:

- Products which do not to meet the required specifications according to the customer or, products which do not meet the required specification of the retailer.
- Products which have been returned due to damage or defective packaging, marketable or administrative factors, or as a result of customer complaint or similar.
- Withdrawal of a certain batch(es) from commercial sale occurs in association with the Product Recall procedure.

Re-Dressing:

It is defined as repacking of a material/product without disturbing its original inner bag (Primary packing material) by only changing its label or external container (secondary packing material) for commercial purpose

References documents:

231.Annex 1: Form Returned Goods Verification Record

8. 231.Annex 2: Labels – Returned Goods Quarantine Label

8.231.Annex 3: Form - Returned Goods Logbook

8.231.Annex 4: Labels - Product Identification Labels, Rejected, Blocked, Released

SOP for Clearance of lines, Area and Equipment

Special note for SMEs:

This note is a general guidance for SMEs as it may not always be possible to practically follow this SOP diligently as suggested by GMP.

Testing in a laboratory is usually not possible to check for integrity of packaging. If the product is still sealed and there are no major defects, it may be re-sold. Should the seal have been broken, it is better to discard the product. If the product has been stored inappropriately or is past its shelf life/ close to sell-by date, discard the product as well.

8. 231. Annex 1: Form Returned goods verification record

Returned Goods Verification Record			
Name of product:		Batch no.:	
Manufacture date:		Expiry date:	
Dispatch tracking no.:		Dispatch date:	
Quantity dispatched:		Date of return receipt:	
Wt. (weight) of return qty. (where applicable):		Quantity received (no.):	
Total no. of container		Label authenticity:	
Seal no. (if any):		Seal integrity:	
Goods returned from:			
Reason for returning:			
Conditions of returned goods:			
Any other observations:			
Documents handed over to QA: *Yes/No*			
Done by:		Checked by:	
Name:		Name:	
Sign:		Sign:	
Quality Assurance:			
To be packed		**Not to be packed**	
Condition:	Recommendation:	Condition:	Recommendation:
Sampling and retesting required	*[Yes/No]*	Product is not satisfactory	*[Yes/No]*
Only redressing is required	[Yes/No]	Product shelf life is less than six months	[Yes/No]
Repacking to be done without retesting	*[Yes/No]*	Quantity is much less	*[Yes/No]*
Any other:			
Reason for recommendation:			
Remarks:			
Recommended by: *(Production/Packing Head)*		Recommended by: *(QA Head)*	
Name:		Name:	
Sign:		Sign:	

Quality control:					
Name of the product:			Batch no.:		
Manufacture date:			Expiry date:		
Serial. no.:	**Test:**	**Finish product analysis result:**	**Retest analysis:**	**% Deviation from the previous result**	**Remarks: (comply/not comply)**
1.					
2.					
3.					
4.					
5.					
Quality assurance:					
Recommended by: (Quality Assurance)			Approved by: (QA Head)		
Name:			Name:		
Sign:			Sign:		
Packing:					
Product name:			Batch no.:		
Materials receipt from:			Quantity receipt from:		
Packing started on:			Packing completed on:		
Batch packing record closed on:			Date of transfer:		
Qty. transferred to [Enter Title] :			Total no. of shipper transferred		
Approval: (Only in case if the batch is to be discarded)					
Approved by: (QA Head)			Approved by: (Plant Head)		
Name:			Name:		
Sign:			Sign:		

Special note for SMEs:

There might not be a designated QA person. In such a case, the owner is probably the one to make the final decision.

8. 231. Annex 2: Labels – Returned goods quarantine label

Returned Goods Quarantine Label	
Sales return no.:	
Product name:	
Batch no.	
Date of return:	
Net weight:	
Container no.:	
Sign: Date: __/_____/_____	

8. 231. Annex 3: Form - Returned Goods Logbook

Returned Goods Logbook						
Serial. no.	Product Name	Batch no.	Manufacture no.	Expiry date	Hold month*	Date of receipt return
Bulk material returned from	Return qty	Proposed action	Date of dispatch/reject	Qty. dispatch/reject	Closure:	Remarks:

8. 231. Annex 4: Labels - Product identification labels, rejected, blocked, released

Product Identification Labels: [NB: It is best to make use of a color-coding system for the labels e.g. green: released, yellow: blocked, red: rejected.

Company logo and title:

Product Name_____ Supplier Name: _____

Producer Name: _____ Recipient Name: _____

Date: _____ Batch Reference: _____

8.5. Returns – SOP 235: Finished goods withdrawal/retention

Logo	**Standard format for SOP:** Finished goods withdrawal/retention Department: _____ Policy No: _____

Company header: _____

Policy: _____

Raw Materials- Laboratory Testing and Documentation

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to lay down the procedure for withdrawal/retention of finished goods in cosmetic production

Scope:

This SOP is applicable for withdrawal and retention of finished goods from production processes.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The QA department is responsible for withdrawal and retention of finished goods.

Accountability:

The head of QA shall be held accountable for compliance of this SOP.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Control sample shall be withdrawn from each batch of product manufactured.
   1.1. Quantity of sample shall be withdrawn in accordance to the table below:

Serial .no	Sample	Quantity of sample drawn (in unit) *
1	Lotion	200
2	Cream	200
3	Essential oil	200

   1.2. The QC staff collect the control samples in accordance with the table from each batch of finished goods throughout the packing procedure and enter the information in the Product Control Sample Logbook.
   1.3. When raw material samples are retained, the QC staff extrapolate the sample and record the information in the Raw Material Retention Sample Logbook.

1.4. The sample is labelled with the control sample sticker on each pack.
1.5. The Control Sample should be a proportional representation of the variety of pack sizes of the same batch.
1.6. Solvent and liquid samples are not to be kept in the Control Sample room.

2. 2. Storage
   2.1. Storage temperature for the control samples [25°C]
   2.2. The storage temperature should be monitored, maintained, and recorded.

3. Physical analysis of the control sample
   3.1. Conduct the sample analysis every six months and record the results in the relevant file.
   3.2. The analysis should include (but not limited to) the following points:
      3.2.1. Description of physical appearance
      3.2.2. Quality of packing
      3.2.3. Imprinting
      3.2.4. Overprinting
      3.2.5. Integrity of packaging

Definitions:

References documents:

SOP for handling of returned Goods.

Special note for SMEs:

"Quantity of sample drawn" as described in the procedure may be unrealistic/impossible for SMEs. If only one litre of essential oil was bought, taking a 200 ml sample makes no sense. Rather take a sample that is still large enough where you can run some diagnostic tests - i.e., enough sample for you to assess colour, smell, texture, etc. after some time has passed. Do this only if a customer complains. The same principle applies to the products.

9

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

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Table of Contents

Chapter 9. Quality control laboratory

Introduction

The GMP standard is an integral division of Quality Assurance which ensures that the products are manufactured and controlled consistently and reliably. Consistency of production is very important and can only be achieved by detailed instructions of the procedures. In particular, GMP focuses on the risk of cross-contamination and mix-ups which cannot be entirely coordinated by testing the final product. By implementing a well-established system that take these risks into consideration, the chance of these occurrences may be reduced. It is imperative that the quality checking system is set up with the risks in mind, and for investigating oversights.

If products are affected by light for example, oxidation, opaque packaging material should be considered. Shipping documentation should capture product, quantity, shipping conditions (duration, temperature, humidity), and special precautions, for example, what to do in case of excessive delays or severe changes in weather.

Objectives

The main purpose of this module is to address the key aspects of quality assurance, thereby understanding the specific requisites for organisation, practices, processes and resources.

Principles

Each cosmetic manufacturing company should have a Quality Assurance department. The Quality Assurance acts independently from the rest of the departments. However, should the company not have such a facility, it is permissible to appoint an external laboratory institution. The Quality Assurance department should operate under the authority of a qualified and experienced individual with one or several control laboratories at his or her disposal. Delivery of quality is collectively referred to as quality assurance. Please note the definitions provided in Chapter 1 and 2 too.

Scope

Quality laboratory control includes sampling, examining and the testing of material throughout the production process, i.e. starting material, intermediate material, bulk material and finished goods. In addition, this module also covers a review of batch documentation, sample retention programs, stability studies and preserving specification of material and finished products, where necessary.

Test methods

The cosmetic manufacturer ensures that all the tests are executed in accordance with test methods outlined in the specifications. The test may be conducted by the cosmetic manufacturer's laboratory or an external laboratory. If the test in conducted by the cosmetic production company, there should be a designated laboratory facility available to carry out the tests. Records must be kept of the testing rationale. The Quality Control laboratory makes use of approved test methods, which matches the acceptance criteria of the product. In order to confirm that the product complies with the acceptance criteria, all of the defined test methods and procedures must be carried out. The results obtained from the Quality Control tests will be compared to the specified acceptance criteria for raw material, bulk material and finished products.

Acceptance criteria

The manufacturer ensures there is an acceptance criteria for raw material, packaging material, bulk products and finished products. The acceptance criteria should be well-defined to meet the GMP specifications. The criteria can be controlled by reviewing all the necessary documents. These include: the manufacturing records, any deviation records and measures that were put in place as a result of the deviation, by checking the sample test results i.e. physical, chemical and microbiological. Additionally, a batch sample should be checked for conformity against the product specification. Finally, the Certificate of Analysis should be approved, and the final product may be labelled "Released" or "Rejected".

Results

The results collected from the acceptance criteria as well as the sample test results are investigated and reviewed before the product can be released. There should be a SOP outlining the entire investigation process. An investigation SOP consists of a review of the method of test procedure conduct, statistical analysis in the form of charts or columns and a review of the history of the item. An expert should be appointed to the task of investigation. The documentation for retesting and re-sampling is then made available.

Out-of-specification results

The cosmetic manufacturer ensures that all documentation concerning the Out-of-Specification process are up to standard and readily accessible. The results must be approved or rejected by the Head of Quality Control. If approved, the material is "released" and authorisation is granted. Any OOS investigation is authorised by the relevant authority before it can be carried out.

Reagents solutions, reference standards, culture media

The reagents used for testing samples are prepared by following the written instructions on SOP. In addition, the cosmetic manufacturer ensures that the storage instructions of the reagents are adhered to. The reagents used must be certified by the original producer. There should be a safety manual available for the use of reagents and chemicals. Separate incompatible substances to avoid chemical reactions, that is, fire, explosions, poisonous gases. Flammable liquids, volatile toxics and odoriferous chemicals should be kept in ventilated cabinets. All reagents, solutions, reference standards and culture media should be closed and returned to their respective storage places after use. Avoid spills and contamination. Lastly, the reagent solutions, reference standards and culture media should be labelled with the following information:

- Name
- Concentration
- Expiry date
- Date of preparation
- Prepared by
- Material Safety Data Sheet

Sampling

Key considerations for this section include, sampling process, sampling plan, sampling tools and the retained sample. The sampling must be performed according to the sampling SOP (chapter 8).

Sampling process

The process involves the use of proper tools/equipment. Material to re-close or seal the package, such as re-sealing tape, should be used. The sealing sticker/tape indicates that of the contents of the product was removed. The containers which have been set aside for sampling should be cleaned. The storage container, used for the sample, complies with the storage requirements of the sample and should not have any effect on the properties of the sample. The tools for microbiology sampling are sterilised before use and an aseptic practice be upheld throughout the sampling procedure.

The plan for sampling should be based on a specified sampling standard such as "the N plan", "the P plan", "the R plan." These correspond to particular formulae utilised for sampling. The sampling plan for packaging material must be in compliance with the specific sampling standards, e.g. British Standards BS 6001-1, ANSI/ASQCZ1. 4-1993.

Sampling tools

This usually includes a scoop for solid samples, a dip tube for liquid samples, and a weighted container for lowering into large tanks. Other sampling instruments include knives, handsaws, pliers, hammers, wrenches and a vacuum cleaner to remove dust residue.

Retained sample

This must be representative of the entire batch of material/products of which it was extracted from. The amount of retained sample extracted should be enough to carry out at least two full re-examinations. For every batch of finished products, the retained samples must be extracted at specified periods.

Checklist: Chapter 9. Quality control laboratory

Chapter 15 Change **control checklist**							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	9.	**Quality Control Laboratory**					
	9.1	**Principle**					
236	9.1.1	Do the principles described for personnel, premises, equipment, subcontracting and documentation also apply to the quality control laboratory?					
237	9.1.2	Is the quality control laboratory responsible for sampling, controls and releases according to defined acceptance criteria?					
	9.2	**Test Methods**					
238	9.2.1	Does the quality control laboratory use all test methods which are necessary to confirm that the product complies with the acceptance criteria?					
239	9.2.2	Are the controls performed on the basis of defined, appropriate and available test methods?					
	9.3	**Acceptance Criteria**					
240*	9.3	Have acceptance criteria for raw material, packaging material, bulk products and finished products been defined to meet the requirements?					
	9.4	**Results**					
241	9.4a	Are the laboratory results documented?					
242	9.4b	Are the laboratory results reviewed?					
243	9.4c	Is this review used to decide a release or rejection or a temporary suspension of the decision (quarantine)?					
244	9.4d	Are the decisions, which are derived through control results, adequately documented?					
	9.5	**Out-of-Specification Results**					
245*	9.5.1	Are the out-of-specification results reviewed by authorised personnel and properly investigated and is a corresponding decision about uses taken subsequently?					
246*	9.5.2	Is any retesting sufficiently justified?					
247	9.5.3	After the new investigation, is a decision, in terms of deviation or rejection or pending, made by authorised personnel?					
	9.6	**Are Reagents, Solutions, Reference Standards, Culture Media – identified through**					
248*	9.6a	- name?					
249	9.6b	- concentration or strength?					
250	9.6c	- expiry date?					

Chapter 15 Change **control checklist**							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
251	9.6d	- name and / or signature of the person who prepared it?					
252	9.6e	- opening date?					
253	9.6f	- storage conditions?					
254		- labelling according to the Hazardous Substances Ordinance?					
	9.7	**Sampling**					
255	9.7.1	Is sampling performed by authorised personnel?					
	9.7.2	**Has the following been defined for sampling:**					
256	9.7.2a	- sampling method?					
257	9.7.2b	- equipment to be used?					
258	9.7.2c	- amounts to be taken?					
259	9.7.2d	- any precautions to be observed to avoid contamination or deterioration?					
260	9.7.2e	- identification of sample?					
261	9.7.2f	- frequency of sampling?					
	9.7.3	**Do the samples include (for clear traceability):**					
262	9.7.3a	- name or identifying code (material number)?					
263	9.7.3b	- batch numbers, own and supplier's / manufacturing numbers?					

Reference:

IKW Cosmetics GMP based on ISO 22716

Website References:

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

Product Specification Sheet Format | Example | Samples | Excel File | Word Document: http://www.inpaspages.com/product_specification_sheet.html

Pharmaceutical guidelines Sop for preparation of Reagent Solutions: https://www.pharmaguideline.com/2008/03/sop-for-procedure-for-preparation-of_4.html

Pharmaceutical guidelines SOP for OOS results: https://www.pharmaguideline.com/2010/03/sop-for-out-of-specification-oos.html

SOP 240 - Acceptance criteria of Raw material, bulk material, packaging material, bulk products and finished products

Logo	**Standard format for SOP:** Acceptance criteria of raw material, bulk material, packaging material, bulk products and finished products Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the defined criteria for acceptance for raw material, bulk material, packaging material, bulk products and finished products.

Scope:

This SOP is applicable to all processes in raw material, bulk material, packaging material, bulk products and finished products.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

- Production supervisor- in charge of all activities in relation to production.
- Quality Controller- must ensure that the product meets the criteria.
- [Company Name] manufacturing employees - must ensure the products are manufactured in accordance with the acceptance criteria

Procedure:

1. Raw Material
   - 1.1. Before use, all raw material must be verified.
   - 1.2. The verification consists of the confirmation and checking of the certificate of analysis from the manufacturer against the approved specification.
   - 1.3. The person in charge of receiving raw material examines the characteristics of the material and package and checks that the identification on the package label and the contents match.
   - 1.4. The person in charge examines the state of the primary packaging to ensure that there are no signs of leaks, no damages or tears and no parts of the internal contents exposed. Additionally, the person in charge must check the seal integrity of the package.

1.5. The person in charge ensures that the label containing the identification and batch number of the material is clear and legible.

1.6. The person in charge of receiving raw material ensures that the above criteria has been checked and verified for each batch to be used in the manufacture of cosmetics.

2. Packaging material/bulk material/products:

2.1. The person in charge conducts the analysis or tests of packaging material/bulk material/products at the defined time and location.

2.2. The person in charge ensures that the results comply with the established process specifications and acceptable criteria.

2.3. The person in charge ensures that line clearance is exercised on all packaging and bulk material or product lines.

2.4. Where applicable, there should be a standard reference labelling and coding format requirement available.

3. Finished products:

3.1. The person in charge checks BMR to ensure that all product documentation is up to date.

3.2. Where applicable, the person in charge follows up on all non-conformance or deviation documents attached to the BMR and checks that the reprocessing or rework instructions were carried out and completed.

3.3. Where applicable, the person in charge reviews all documentation on microbiological, physical and chemical tests which have been conducted on the finished product.

3.4. Upon approval of the Certificate of Analysis, the finished product may be labelled with the status "released" or "rejected".

Reference documents:

SOP for handling of returned Goods.

SOP 245 - out-of-specification investigation

SOP 322 – Corrective Actions and Preventive Actions (CAPA)

SOP 337- Product Recall Procedure

Special note for SMEs

It is advisable to include specifications for raw material, packaging, finished products, etc., directly in the BMR for ease of use. Make provision for a section in the BMR that lists all the specifications for the material and product s that must be ticked off before, during and after production. (Makes the documentation a lot easier and provides better overview.)

SOP 213 - Specification of starting material, processing water and finished product

Logo	**Standard format for SOP:** Specification of starting material, processing water and finished product Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title : _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Specification Control
   1.1. The Quality Control official shall be responsible for the following:
      - Approval of each specification
      - Sign and date each specification
      - Maintain the records of each specification
   1.2. The Quality Control official maintains the specification records for the following:
      - Starting material
      - Process water
      - In-process
      - Finished product
      - Master formula
      - Batch Manufacturing Record (BMR)

2. Starting/raw material specification: [to be determined by the manufacturer, depends on the product to be produced, i.e., each kind of product must correspond to a certain specification].
   2.1. The QC official ensures that the specification for starting material includes the following:
      - Assigned name
      - Internal code and reference where necessary
      - Qualitative/quantitative requirement with acceptance parameters
      - Supplier and the original producer
      - Sampling and testing guidelines or reference to an approved instruction manual
      - Guidelines on precautions and conditions of storage
      - Instruction on storage period prior to re-examination
3. Processing Water Specification:
   3.1. During cosmetic processing, drinking water shall be designated as the minimum standard of use.
   3.2. A compatible specification of chemical and microbial quality shall be established based specifically on the point of use of the water.
   3.3. Tests shall be conducted on a periodic basis, e.g., weekly.
   3.4. Depending on the requirements of the product formula, process, and claim, it may be necessary to carry out further treatments to the water.
   3.5. Specification for water with further treatment shall be established based on supplier design specification or pharmacopoeia standards.
   3.6. The company shall be responsible for a careful review of the quality of water to be utilised, particularly in cases where 90% of the product content consists of water. In cosmetic manufacturing, choice of water quality will have a significant impact on the final product's quality and stability.
   3.7. For production of baby products, or products used near to the eye area, mucus membrane and oral cavity, the company shall make use of de-ionised water.
4. Finished Product Specification:
   4.1. The specification for finished goods shall include the following:
      - Designated name, and internal code reference if applicable
      - Formula number
      - Description of finished product and its package details
      - Qualitative and quantitative requirement with acceptance limits
      - Direction for sampling and testing, or reference to an approved procedure
      - Storage condition or precautions if any
      - Shelf life if any
      - Batch numbering requirement (including manufacturing date or expiry date)

Definitions:

Reference documents:

8.213.Annex 2: Form – Product specification 2

SOP 245 - out-of-specification investigation

SOP 322 – Corrective Actions and Preventive Actions (CAPA)

SOP 337- Product Recall Procedure

8.213. Annex 2: Form – Product Specification 2

Product specification sheet		
Format no.:		
Product ID:	Product specification no.:	Product specification record sheet no.:
Formula no:	Internal code:	Reference code: (if applicable)
Product name:		
Product characteristics	**Specifications/characteristics descriptions**	
Standard reference:		
Mechanical/physical characteristics:		
Chemical compositions:		
Biological compositions (if applicable):		
General condition:		
Application/ intended use:		
Safety requirements:		
Handling requirements:		
Storage requirements:		
Basic preparation requirements:		
Usage requirements:		
Method of storage/handling/distributions:		
Legal / applicable Acts and Statutory Regulatory complaints:		
Shelf life (if any):		
Batch no:	Mfg. date:	Expiry date:
Prepared by:	Approved by:	

SOP 272 - Investigation of out of specification products and material

Logo	**Standard format for SOP:** Out-of-specification investigation Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the procedure for investigation of OOS results obtained during analysis.

Scope:

This SOP is applicable to the results of OOS which is obtained from the QC laboratory for raw and packaging material, finished products for releasing parameters not withstanding informative parameters.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Control Analyst informs the Quality Control Supervisor of OOS results.

The Quality Control Supervisor issues the OOS investigation form after entering results in the OOS logbook.

The Quality Assurance conducts the OOS investigation on results.

Accountability:

Head of Quality Assurance shall be held accountable for the verification of the investigation form at each level and shall generate a final conclusion regarding the status of the material(s).

Procedure:

1. Laboratory investigation guiding principles:
   - 1.1. Once the QC supervisor receives the OOS results from the QC analyst, it is recorded in the logbook and an OOS form is issued.
   - 1.2. The QC supervisor shall conduct the investigation and complete the form (level 1)
   - 1.3. If Level 1 was found unsatisfactory, the error is corrected, and the supervisor sends the same material for re-analysis to another Senior Analyst. (Level 2).
   - 1.4. If the material meets the requirements, the material is released.
2. Retesting

2.1. If the factors of level 1 are found satisfactory, the material is designated for re-analysis by the supervisor (level 2).

2.2. If the material passes level 2, the material is re-analysed by the first analyst with the same sample material and the result of the first analyst is investigated simultaneously.

2.3. If the data results of both analysts were found adequate, the material is released.

3. Resampling

3.1. If the material does not pass level 2 under the Senior Analyst as well, conduct a re-sample analysis with the previously approved material in level 3.

3.2. (Level 3) re-sampled material must be executed under authorisation of the Head of Quality Control before further analysis may be conducted.

4. Outlier tests

4.1. Level 3 is not applicable to the following:

- First time received material
- Where no previous sample is available
- Where the material was previously approved but the material under investigation fails to meet the specification

In all the above cases the material shall be rejected.

4.2. If the previously approved material and the material under investigation both meet the specifications, the analyst conducts a re-analysis and investigation of the second analysis in level 2.

4.3. If after re-analysis the material is found satisfactory, the material is "released".

5. Documentation

5.1. The repeat analysis is documented on a separate sheet provided by the supervisor.

5.2. Repeat analysis is authorised by the supervisor before proceeding.

5.3. All printouts should be attached to the OOS Investigation Form.

5.4. Cross-references of analysis should also be attached to the OOS investigation Form.

6. Conclusion of analysis results.

6.1. The final conclusion is to be recorded in the OOS Investigation Form.

6.2. The final conclusion must be rejected/approved by the Head of Quality Control.

6.3. Cross references of the OOS Investigation form should also be included in the analytical report.

Definitions:

OOS: Out-of-specification

Reference documents:

8.213.Annex 2: Form – Product specification 2

SOP 245 - out-of-specification investigation

SOP 322 – Corrective Actions and Preventive Actions (CAPA)

SOP 337- Product Recall Procedure

10.272. Annex 1: Form – OOS investigation

OOS Investigation Form- General Details	
Form no:	Issued by:
Issued to:	Date:
Product/item:	
Batch no./ lot no:	
Stage:	
Out of specification test:	
Analysed by:	
Date:	
Reference:	

Details of Investigation

Step 1

Serial No.	Item	Checked	Observation	Sign
1.	Sample condition?	☐		
2.	Scale balance calibrated?	☐		
3.	Instrument calibration?	☐		
4.	Volumetric standard/ reagent used for analysis checked for its validity?	☐		
5.	Working standard validity?	☐		

Investigator remarks: (satisfactory/unsatisfactory).

Signature: Date:

Step 2

Repeat analysis approved/forwarded to:	
Date:	
Observation of the result:	
Signature:	

Date:	

NB: if the material does not pass level 2, authorisation is given and the material resampled. The analysis is carried out by the Senior Analyst with the previously approved material.

Material/product resample authorisation form				
AR Number:	**Quantity:**	**Authorisation:**	**Sampled by:**	**Date:**

Step 3		
Name of the Senior Chemist:		
Date of analysis:		
Approved batch taken for comparison:		
Observation of the result:		
Approved batch:		
Current batch:		
Analysed by:		Date:
Reference:		
Final Conclusion:		
Head of quality:		Date:
Sections Level 1: Level 2: Level 3:		
Investigation report:		

SOP 248 for Preparation of reagent solution

Logo	**Standard format for SOP:** Preparation of reagent solution Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of Area _____ Page _____ of_____

SOP Number _____ Title _____

Revision Number _____

Written by _____ Edited by _____

Authorisation signature _____ Department _____Date _____

Effective Date: _____ Replaces: _____

Purpose

The purpose of the SOP is to define the instructions for the preparation of reagent solutions.

Scope

This SOP is applicable to the department of Quality Control.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility

This SOP is the responsibility of the Quality Control Supervisor.

Accountability

Senior Manager of Quality Assurance

Material and equipment

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure

1. The reagent solution may not be prepared unless it is required.
2. The reagent solution must be prepared by the same analyst who will conduct the sample analysis.
3. The volume and measurements used will be dependent on the test requirements.
4. Follow the preparation instructions as written in the relevant procedure.
5. The reagent shall be prepared with distilled water.
6. Reagent solution storage criteria:

   Each reagent shall have a label indicating the following information:

   - Name
   - Potency

- Normality
- Molarity (if available)
- Prepared by: title
- Preparation date
- Use before date
- Signature

7. Once prepared, the reagent solution may be used for 3 months after the preparation date.
8. If any defects have been discovered within the 3-month period, the reagent solution shall be replaced by a fresh solution and prepared as per requirement only.
9. Prior to preparation, the Quality Analyst shall be required to conduct research on the determination of shelf life of the solutions in the laboratory.

Definitions

OOS: Out-of-specification

Reference documents

9.248.Annex 1: Label - Reagent Solution

SOP 214 - Sampling finished Goods

9.248. Annex 1: Label - Reagent solution

Name of Reagent:	
Potency:	
Normality:	
Molarity:	**(If applicable)**
Date of preparation:	**Use before date:**
Prepared by:	**Sign:**

10

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 10: Treatment of products that are out-of-specification

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
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	Date	By (Name and Position)	Signature
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Table of Contents

Chapter 10. Treatment of products that are "out-of-specification" or non-compliant

Introduction

A product may be "out of specification" or noncompliant, if the examination, measurement or test result does not comply with the defined acceptance criteria (Finished Products Chapter 8). The cosmetic manufacturer should have an established system to regulate the handling of rejected finished products, bulk and raw, and packaging material. This system includes investigations conducted by authorised personnel, followed by approved procedures. Thereafter, based on the investigation results, the quality control department will decide on what further action should be taken. If the decision is taken to reprocess the product, then the methods and performance of reprocessing must be specified and approved by the authorized personnel in the Quality Control Department. The cosmetic manufacturer ensures that the reprocessing of finished products and bulk products is regulated by an established system which is monitored by authorised personnel to ensure that the product complies with the defined acceptance criteria.

Product out of specification (POOS) can be caused by for example, production equipment malfunctioning, operator/human errors, process and manufacturing errors and uncontrolled environment.

To minimise errors, proper controls should be put in place include the following:

- Standard operating procedures
- Properly trained and supervised personnel
- Properly calibrated instrumentation
- Well-maintained equipment.

Principle

To ensure that there is an established and well-documented system in place for handling any noncompliance which may have occurred during production. To ensure that there are qualified individuals to conduct these procedures. To ensure traceability of products or materials which have been identified as noncompliant.

Scope

This chapter covers the treatment or handling of Rejected Finished Products, Bulk Products, Raw Materials and Packaging Materials that are out of the defined specification of chapter 8 (finished Products). Furthermore, the procedures for Reprocessed Finished Products and Bulk Products will also be discussed in this chapter.

Purpose

The purpose of this chapter is to ensure that the cosmetic manufacturer has an established system in place for the handling of finished products, bulk products, raw materials and packaging materials. Products and materials that are out of specification or noncompliant should be regulated and reviewed by authorised quality control personnel to ensure compliance with the defined acceptance criteria.

Rejected finished products, bulk products, raw material and packaging material

The cosmetic manufacturer ensures that all investigations related to "out of specification" or noncompliant products and/or materials are reviewed and approved by authorized personnel in the Quality Control Department. The investigation procedures are well documented and readily available. An investigation comprises a re-evaluation of the calculations to identify and rectify any errors, re-evaluation of all apparatus and analytical data of the product or material, and of previous samples of the product or material, as well as re-evaluation of the reagents used for the tests. Additionally, the appointed personnel conduct a detailed investigation and assessment of the original results before re-testing. The re-testing and re-sampling process and results are well-documented and filed.

Reprocessed finished products and bulk products

When a batch or part of a batch fails to meet the defined specifications, it can be reprocessed by means of an alternative manufacturing or packaging process or, reprocessed by means of the previous step of the approved manufacturing or packaging process. It is important to ensure that quality control personnel are allowed access to production sites to carry out sampling and other investigations. The reprocessing of rejected products should be exceptional. It is only permitted if the quality of the final product is not affected. Investigation should suggest a reprocessing method for example, incorporation into a batch of the same product at a defined stage of manufacture. However, always bear in mind that adequate restrictions to highly dangerous zones are required. Before reprocessing can take place, an OOS investigation (out of specification/noncompliant) must be conducted and approved by the Quality Control Authority. This is based on an approved procedure. The requirements for reprocessing indicate who is responsible and which tasks are assigned to that individual, sampling plan, and the acceptance criteria for that specific product/material. Once the investigation has been completed, the reprocessing instruction is signed and approved by the appointed Quality Control Officer. It may be necessary to include a stability report as part of the reprocessing instructions. Stability may be outsourced to an approved testing laboratory, or the cosmetic manufacturer conducts the test in-house.

Chapter 10 Checklist for treatment of products that are OOS

Chapter 10 Treatment of products that are OOS checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	10.	**Treatment of Products that are Out of Specification**					
	10.1	**Rejected Finished Products, Bulk Products, Raw Materials and Packaging Materials**					
264*	10.1.1	Are investigations of rejected finished products / bulk products or raw materials / packaging materials performed by personnel authorised to do so?					
265	10.1.2	Is the decision about rejected products / materials (destruction, reprocessing) taken by the personnel responsible for quality?					
	10.2	**Reprocessed Finished Products and Bulk Products**					
266*	10.2.1	Is the decision to reprocess, rework or mix (bulk) products which are not conform, only taken by the personnel responsible for quality?					
267	10.2.2	Is the method of reprocessing defined and approved?					
268	10.2.3	Are controls performed on the reprocessed finished products or bulk products by authorised personnel and are the corresponding results reviewed in order to verify the conformity with the acceptance criteria?					

Reference

IKW Cosmetics GMP based on ISO 22716

Website References

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

15th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

15th September 2021

Pharmaceutical guidelines SOP for OOS results: https://www.pharmaguideline.com/2010/03/sop-for-out-of-specification-oos.html

15th September 2021

Docplayer Manufacturing rework procedure: https://docplayer.net/21088350-Standard-operating-procedure-title-manufacturing-rework-procedure.html

15th September 2021

10.1. SOP 272 - Investigation of out of specification/noncompliant products and materials

(This SOP is also required under Chapter 9 where it deals with testing, in this chapter it deals with the investigation around non-compliance)

This SOP is repeated here; while SOP 272 refers to procedures for recalls testing in a lab situation, this SOP refers to the authorities required to declare a product non-compliant, and therefore to be rejected.

Logo	**Standard format for SOP**: Out-of-specification investigation Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the procedure for investigation of OOS results obtained during analysis.

Scope:

This SOP is applicable to the results of OOS which is obtained from the QC laboratory for raw and packaging materials, finished products for releasing parameters not withstanding informative parameters.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Control Analyst informs the Quality Control Supervisor of the OOS results.

The Quality Control Supervisor issues the OOS investigation form after entering results in the OOS logbook.

The Quality Assurance conducts OOS investigation on results.

Accountability:

The Head of Quality Assurance is held accountable for the verification of the investigation at each step and generates a conclusion concerning the status of the material(s).

Material and equipment:

Procedure:

1. Laboratory investigation guiding principles:
   - 1.1. Once the QC supervisor receives the OOS results from the QC analyst, it is entered in the logbook and an OOS form is issued.
   - 1.2. The QC supervisor conducts the investigation and completes the form (step 1).
   - 1.3. If the results of step 1 were found unsatisfactory, the error is corrected. The same material will be sent for testing and/or re-testing (step 2).
   - 1.4. If the material meets the requirements, the material is released.
2. Retesting
   - 2.1. If the factors of step 1 are found satisfactory, the material is marked for re-analysis by the supervisor (step 2).
   - 2.2. If the material passes step 2, the material is re-analysed by the first analyst with the same sample material and the first analyst's results are investigated simultaneously.
   - 2.3. If the report of the first analysts is termed satisfactory, the material is released.
3. Resampling
   - 3.1. If the material does not pass step 2 by the senior analyst as well, conduct a re-sample analysis with the previously approved material in step 3.
   - 3.2. (Step 3) re-sampled material is executed with the authorisation of the Head of Quality Control before further analysis may be conducted.
4. Outlier tests
   - 4.1. Step 3 is not applicable to the following:
     - First time received material
     - Where no previous sample is available
     - Where the material was previously approved but the material under investigation fails to meet the specifications

   In all the above cases the material is rejected.
   - 4.2. If the previously approved material and the material under investigation both meet the specifications, the second analyst conducts a re-analysis and investigation of the second analysis in step 2.
   - 4.3. If after re-analysis the material is found satisfactory, the material is released.
5. Documentation
   - 5.1. The repeat analysis is documented on a separate sheet provided by the supervisor.
   - 5.2. Repeat analysis is authorized by the supervisor before proceeding.
   - 5.3. All relevant documentation is attached to the OOS Investigation Form.
   - 5.4. Cross-references of analysis are also be attached to the OOS Investigation Form.
   - 5.5. The record should include the following:
     - 5.5.1. Clearly identify the reason for the investigation
     - 5.5.2. Summarise the manufacturing process sequences that might have caused the problem
     - 5.5.3. Indicate actual or probable cause
     - 5.5.4. Determine if the problem has occurred previously
     - 5.5.5. Describe any corrective actions taken
     - 5.5.6. Include a list of other batches and products possibly affected
     - 5.5.7. Any required corrective actions and comments
     - 5.5.8. Signatures of appropriate personnel.
6. Conclusion of analysis results.
   - 6.1. The Final Conclusion is recorded in the OOS Investigation Form.
   - 6.2. The Final conclusion is rejected/approved by the Head of Quality Control.
   - 6.3. Cross references of the OOS Investigation Form should also be included in the analytical report.

Definitions:

OOS: Out-of-specification

Major defect: non-conformity of a product which is evident to the consumer and is non-hazardous or barely hazardous. For example, microbiological contamination of products with low consumer risks, the cosmetic product is of sub-standard quality, insufficient labelling information or warning of hazards to consumers.

Critical defect: a defect which is life threatening and requires immediate attention irrespective of company business hours. For example, the product has been deliberately tampered with or counterfeited or, the product has been labelled incorrectly.

Minor defect: a defect which does not have a significant impact on the use of the cosmetic product and is non-hazardous. For example, the absence of a label or packaging.

Reference documents:

10.272. Annex 1: Form – OOS investigation

SOP 338 - Change control Procedures

SOP 322 – Corrective Actions and Preventive Actions (CAPA)

SOP 337- Product Recall Procedure

10.272. Annex 1: Form – OOS investigation

OOS Investigation Form- General Details	
Form no:	Issued by:
Issued to:	Date:
Product/item:	
Batch no./ lot no:	
Stage:	
Out of specification test:	
Analysed by:	
Date:	
Reference:	

Details of Investigation

Step 1

Serial no.	Item	Checked	Observation	Sign
1.	Sample condition?	☐		
2.	Scale balance calibrated?	☐		
3.	Instrument calibration?	☐		
4.	Volumetric standard/ reagent used for analysis checked for its validity?	☐		
5.	Working standard validity?	☐		

Investigator remarks: (satisfactory/unsatisfactory).

Signature: Date:

Step 2

Repeat analysis approved/forwarded to:	
Date:	
Observation of the result:	
Signature:	

Date:	

NB: if the material does not pass step 2, authorisation is given and the material resampled. The analysis is carried out by the Senior Analyst with the previously approved material.

Material/product resample authorisation form				
AR Number:	**Quantity:**	**Authorisation:**	**Sampled by:**	**Date:**

Step 3		
Name of the Senior Chemist:		
Date of analysis:		
Approved batch taken for comparison:		
Observation of the result:		
Approved batch:		
Current batch:		
Analysed by:		Date:
Reference:		
Final conclusion:		
Head of quality:		Date:
Sections Step 1: Step 2: Step 3:		
Investigation report:		

10.2. SOP 274 - Reprocessing and reworking of rejected goods

Logo	**Standard format for SOP:** Reprocessing and reworking of rejected goods Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the reprocessing method, reprocessing investigation procedures and to control batch deviations/reprocessing/reworking to ensure that efficiency, quality, safety, purity of the product is maintained and that GMP requirements are complied with

Scope:

This SOP covers all cosmetic products manufactured under the GMP standard.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Head of Production identifies the OOS product and informs the QA.

The Head of Quality Control investigates the cause of OOS and observes the disposal procedure.

Procedure:

1. Storage of materials to be reprocessed.

[List of all the storage materials in your company to be reprocessed and additional instructions.]

2. Reprocessing Requirements.
   - 2.1. All reprocessing activities are approved by a QA management member with a change control process following an investigation of the effects on product quality and GMP compliance requirements.
   - 2.2. All reprocessing activities are examined to determine if any further testing or stability tests are required.
   - 2.3. If the reprocessing material is part of the defined specifications, it is documented in the BMR as part of the usual manufacturing process.

2.4. Reprocessing of an intermediate or active cosmetic material is necessary when it is an important factor in the manufacturing process as detailed in the GMP requirements for cosmetics # 22716.

2.5. If the reprocessing activities are OOS in the usual production process, the reprocessing is only conducted under these specified circumstances:

- If the quality of the finished product will not be negatively affected.
- If the specifications described have been fully met.

2.6. The batches produced from these activities are incorporated into the stability procedure of the final product.

2.7. All reprocessed product/material are assigned a new batch number and all applicable documentation is completed.

2.8. The reprocessing documentation includes the reason for conducting a reprocess and are technically justified.

3. Stability

3.1. The stability tests are conducted where necessary.

3.2. Real time stability shall extend to the end of shelf-life period for any new product and includes the following parameters:

- Number of batch(es) for different batch sizes
- Relevant physical, chemical, microbiological test methods
- Acceptance criteria
- Description of the container closure system(s)
- Testing intervals (time points)
- Description of the condition of storage

4. Storage of materials to be reworked.

5. Reworking prerequisites.

5.1. All rework activities are approved by QA and may only be initiated with an approved protocol.

5.2. The protocol is prepared by a QA member. The QA member submits the protocol for approval by the QA Manager.

5.3. The protocol is structured in such a way to closely resemble the usual process of production. The protocol includes checks and tests conducted in the initial production where applicable.

5.4. The reprocessing of rejected products should be exceptional. It is only permitted if the quality of the final product is not affected.

5.5. Investigation should suggest a reprocessing method for example, incorporation into a batch of the same product at a defined stage of manufacture.

6. Rework procedure

6.1. Should a deviation in the production process be found, a Deviation Report is completed. The batch number and area are clearly specified in the report.

6.2. The goods or materials to be reworked are removed from the process area and transferred to an area separate from raw materials and other in-process materials.

6.3. Prior to moving the goods or materials to a separate area, the production operator ensures that the product code and batch numbers are correct. The production operator shall place a sticker on the batch stating "Product to be reworked"

6.4. The rework is conducted in accordance with the rework protocol laid down by the QA member as mentioned in (5.2.) and signed off once completed.

6.5. Thereafter, the rework material/batch is sent along with the protocol to the QA department.

6.6. Each step in the reworking process is documented and the batch documents updated accordingly.

6.7. On completion of the rework the labels will be extracted, and the material cleaned with IPA.

Reference documents:

8.5. SOP 272- Handling of returned Goods.

10.274. Annex 1: Form - Rework Goods return

15.0. SOP 338 - Change control Procedures

13.2. SOP 322 – Corrective Actions and Preventive Actions (CAPA)

14.2. SOP 332 - Complaint Handling Procedure

14.3. SOP 337- Product Recall Procedure

Special note for SMEs:

A modified batch manufacturing record is advisable to support the rework. Sometimes the reworking is not possible and/or too complicated to carry out. In such a case the product should be rejected.

10.274. Annex 1: Form - Rework goods return

Form for products to be reworked					
Production to fill in			**Warehouse to fill in**		
Initial booking slip number:			Checked by:	Sign:	Date:
Prepared by:	Sign:	Date:	Picked by:	Sign:	Date:
Process line:			No. of full lot:	No. of part of lot:	
Product code:			Product code:		
Product description:			Product description:		
Batch production number:			Batch production number:		
Date of Expiry:			Date of Expiry:		
Total amount to be returned:			Total amount selected:		
Number of lot:			Number of lot:		
Number of pallets:			Number of pallets:		
Destination area code			Source storage type/bin		
Transport code:	From:	To:	Transport code:	From:	To:
Production checked by:				Pallet quantity:	

11

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 11: Waste

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
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Chapter 11. Waste

Introduction

During cosmetic manufacturing, large amounts of waste, whether in solid or liquid form, are processed. In some cases, these wastes may have toxic, corrosive or irritant properties. Hazardous waste is generated in every part of the production process; thus it is imperative to promote and facilitate safe working methods when using dangerous chemicals. It is important to have a specific storage area for hazardous waste, while awaiting the disposal to the official authorized disposal area. The method for waste handling and disposal should be in compliance with Namibian legislation.

Principle

The manufacturing company has to comply with local regulations concerning waste disposal. There should be proper and safe storage procedures in place concerning the handling of waste. Toxic and flammable materials or substances used in production should be stored in an enclosed area or room which has been specifically designed for that purpose.

Scope

This chapter is applicable to all areas of the production process which involves the handling of waste. This chapter covers the GMP requirements of the types of waste in cosmetic production, the flow of waste, containers that should be used for waste and disposal procedures for waste.

Purpose

The purpose of this chapter is to ensure that all waste material is handled in a safe manner. The manufacturing company ensures that all waste is stored correctly and safely. Waste should not be allowed to accumulate. The manufacturing company ensures that toxic and flammable materials are stored separately in a room designed specifically for that purpose.

Types of Waste

The cosmetic manufacturer must ensure that for each of the major production stages, there is a clear description of the types of waste generated. The production stage is primarily based on how production will affect the quality of the finished product and this includes quality waste control.

Flow

The cosmetic manufacturer ensures that the flow of waste does not interfere or affect the production processes as well as the QC laboratory. There must be a waste management system in place concerning waste disposal, transportation and storage. This waste management system should be appropriately documented. Waste materials should not be allowed to accumulate at collection points.

Containers

Containers for waste storage must have proper labels with the type of waste, state of waste and the necessary precautions/hazards, in accordance with local regulations. Solid wastes should not be mixed with liquid wastes. Provision should be made for the proper and safe storage of waste material awaiting disposal.

Disposal

Waste must be disposed of correctly and according to the type of waste to be discarded, according to government regulations. The cosmetic manufacturer ensures that the waste is disposed of at regular and prescribed intervals. The destruction thereof should be monitored, and the waste should be disposed of in a safe manner.

Chapter 11. Waste checklist

Chapter 11. Waste checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	11.	**Wastes**					
	11.1	**Principle**					
269	11.1	Is waste disposed of in a timely and sanitary manner?					
	11.2	**Types of Waste**					
270	11.2a	Are the types of waste for the production processes defined which could affect the quality of the finished products?					
271*	11.2b	Are there types of waste defined for the work of the quality control laboratory which could affect the quality of the finished products?					
	11.3	**Flow**					
272	11.3.1	Does the flow of waste impair the operations in production and laboratories?					
273	11.3.2	Have measures been taken in view of the collection, transportation, storage and disposal of waste?					
274	11.3.2	Are the individual measures of collection, transportation, storage and disposal of waste adequately documented?					
	11.4	**Containers**					
275	11.4	Are the waste containers correctly identified (possibly with additional information)?					
	11.5	**Disposal**					
276	11.5	Is the destruction of waste performed in the correct manner?					
*277	11.5	Is the destruction of waste monitored?					

Reference

IKW Cosmetics GMP based on ISO 22716

Website References

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 13th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/
Last viewed 13th September 2021

University of Virginia Waste Management SOP:
https://www.fm.virginia.edu/docs/operations/SOP_WasteManagement.pdf
Last viewed 13th September 2021

ResearchGate Waste generation in manufacturing: https://www.researchgate.net/figure/Flow-chart-of-waste-generation-in-a-manufacturing-process-Source-Meti-2007_fig2_282868214
Last viewed 13th September 2021

11.5.285. SOP - Laboratory Waste Disposal

Logo	**Standard format for SOP:** Laboratory Waste Disposal Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title : _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

This Operator Instruction outlines the steps required for disposal of laboratory waste and guidelines for maintaining the laboratory waste disposal at an acceptable level of GMP.

Scope:

This Operator Instruction covers the Quality Control Laboratory.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

All personnel shall act in accordance with this procedure and also ensure that visitors and contractors do the same. Managers and Team Leaders shall ensure that all personnel are trained, understand and comply with this procedure

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Material Required List:

- Waste disposal containers
- Waste container trolley
- PPE (gloves, lab coat, safety glasses, safety shoes, etc.)
- Waste container labels

Solid waste disposal:

Paper, plastic, glass, finished goods, etc. are to be separated into the relevant coloured waste disposal bins. Recyclable waste must be free of any chemical contaminants or residues.

Procedure:

Chemical Waste Disposal

1. All chemical waste should be categorized before disposal. All chemical waste is stored and discarded separately wherever possible. Safety and environmental services must be contacted before mixing any chemical waste.

2. Specific disposal methods are discussed in the following Flow chart for Types/ Steps of waste management processes (Annexure xxxx).
3. Waste material should be classified according to the main hazardous nature of a waste material.
4. Waste material should be determined by consulting:
   4.1. Material Safety Data Sheets (MSDS),
   4.2. Manufacturer information
   4.3. Supplier information
   4.4. Other laboratory reference material.
5. Organic waste is separated according to the "Flow chart for Chemical waste categories" (Annexure xxxx).
6. All personnel who handle hazardous waste must receive the correct training, and the instructions on MSDS must be followed at all times. All personnel who handle hazardous waste are to wear the correct attire for the type of chemical waste being handled, in accordance with the MSDS instructions for the specified chemical.

Definitions:

Major defect: non-conformity of a product which is evident to the consumer and is non-hazardous or barely hazardous. For example, microbiological contamination of products with low consumer risks, the cosmetic product is of sub-standard quality, insufficient labelling information or warning of hazards to consumers.

Critical defect: a defect which is life threatening and requires immediate attention irrespective of company business hours. For example, the product has been deliberately tampered with or counterfeited or, the product has been labelled incorrectly.

Minor defect: a defect which does not have a significant impact on the use of the cosmetic product and is non-hazardous. For example, the absence of a label or packaging.

Reference documents:

11.279. Annex 1: Flow chart - Chemical waste categories

11.279. Annex 2: Flow chart - Types/ steps of waste management process

11.279. Annex 3: Flow Chart – In-process waste production

11.279. Annex 4: Form - Waste Identification sheet

11.279. Annex 5: Form - Hazardous waste disposal

11.279. Annex 6: Form - Material Safety Data sheet

11.2. SOP 279 - Waste Management Plan

11.2. 279. SOP - Waste management plan

Logo	**Standard format for SOP:** Waste management plan Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title : _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

This Operator Instruction outlines the steps required for disposal of laboratory waste and guidelines for maintaining the This Operator Instruction outlines the steps required for a Waste Management Plan that encompasses the handling of waste in all areas of the cosmetic production line and includes the collection, transportation, storage, and disposal of solid, liquid and gaseous, as well as hazardous and non-hazardous waste according to GMP requirements

Scope:

This Operator Instruction outlines the steps required for a Waste Management Plan that encompasses the handling of waste in all areas of cosmetic production and includes the collection, transportation, storage, and disposal of solid, liquid and gaseous as well as hazardous and non-hazardous waste according to GMP requirements.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

All company personnel shall act in accordance with this procedure and ensure that visitors and contractors do the same. Managers and Team Leaders shall ensure that all personnel are trained, understand and comply with this procedure.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Material Required List:

- Waste disposal containers
- Waste container trolley
- Key to the destruction cage
- PPE (gloves, lab coat, safety glasses, safety shoes, etc.)
- Waste container labels
- Zeofresh spill kit and absorbent mats

Solid waste disposal:

Paper, plastic, glass, finished goods, etc. are to be separated into the relevant coloured waste disposal bins. Recyclable waste must be free of any chemical contaminants or residues.

NB: Personnel who work directly with hazardous or non-hazardous waste should wear personal protective equipment (PPE) in accordance with the information in the Safety Data Sheets.

Accountability:

- Managers and supervisors will be held accountable and must ensure that their staff comply with the waste management plan.
- Each manager shall train their employees with the appropriate disposal, storage, collection and transportation procedure.
- Managers and supervisors shall ensure that the staff are trained in the most recent version of the SOP.
- Personnel, who have been tasked with the identification of types of waste, shall be held responsible and must follow the suitable procedures in accordance with this SOP.
- Personnel shall be held responsible with reporting cases of leakage, damaged or loss of covers, or misappropriation/pilferage of material containers.

Procedure:

1. Types of Waste:
   - The types shall be sorted according to the flow chart (Annexure xxxx) attached to this SOP.
   - The waste shall be dealt with according to the flow chart (Annexure xxx) attached to this SOP.

1.1. Municipal Solid Waste:

- This includes office waste, oil, cloth, pigment sacks, paint cans and any general waste that may be disposed of with municipal services.

1.1.1. Collection - Shall be collected regularly on each [e.g., Monday] of the week.

- Each staff member shall be responsible for depositing their waste into the nearest suitable garbage bin.
- If the waste container is full or material is left next to the container, it is the responsibility of the waste contractor's personnel to reload the containers.
- Any waste container without a lid, or a leaking container must be reported immediately to the municipal contractor at [contact number]

1.1.2. Storage – shall be stored in defined/labelled garbage bins before collection.

1.1.3. Transportation – shall be transported with the municipal contractor's regular service vehicles.

1.1.4. Disposal - is not restricted for special disposal and can be discarded into a waste bin.

- Hazardous chemicals, radioactive and biological waste shall be handled and disposed of separately and is not included with municipal solid waste.

1.2. Universal Waste:

- Examples - batteries and fluorescent lamps.
- Shall be handled in accordance with the Namibian Waste Management Regulations Act.1992.
- Shall be handled in accordance with the Flow chart for Types/Steps for waste management process, Annexure [xxx].

1.2.1. Collection [type of collection procedure which your company uses].

- Fluorescent lights shall be collected regularly on [Thursdays] during the afternoon by [title of contracted company being used].
- Alkaline batteries shall be placed in their terminals and sealed with tape to avoid the possibility of fire.

1.2.2. Storage [type the storage procedure and conditions for the type of waste to be disposed].

1.2.3. Transportation [type the procedure/title of service which your company uses for transporting this type of waste]

1.2.4. Disposal

- Ensure that batteries and other universal types of waste are disposed of in a safe manner, in accordance with the Material Safety Data Sheet completed for each type of waste.

1.3. Recyclable, Recoverable, or Reusable Materials

1.3.1. Collection [type of collection procedure which your company uses].

1.3.2. Storage [type of storage procedure and conditions for the type of waste to be disposed].

1.3.3. Transportation [type of transportation procedure which your company uses].

1.3.4. Disposal [type of disposal procedure which your company uses].

1.4. Cleaning and Wash Water Disposal

- Shall be dealt with in accordance with the nature of the material to be cleaned and site of the cleaning procedure.
- Where applicable, the interior drain shall be utilised in such a way that it is suitable for the disposal into the sanitary sewer.
- Interior drain shall only be used for materials with a pH 6-9, if pH is out of range, dilute with lots of water.

2. Waste deposition in the manufacturing process:

- The manufacturing company shall appoint a staff member to handle the waste in their individual section of the production.
- The type of waste generated from each section of the production process must be defined and the information be included in the Flow chart (annexure xxx) attached to this SOP.
- Each type of waste from the production shall be handled according to the flow chart (Annexure xxx) attached to this document.

3. Staff training for the handling of hazardous/non-hazardous waste:

- Staff must be adequately trained in the handling of hazardous waste.
- Staff tasked with handling hazardous waste must be provided with appropriate attire for handling of hazardous waste.
- Material data sheets must be consulted for detailed instructions on storage and disposal of hazardous waste.
- Hazardous waste must be stored in demarcated areas as per the conditions specified in the MSDS.

Definitions:

Major defect: non-conformity of a product which is evident to the consumer and is non-hazardous or barely hazardous. For example, microbiological contamination of products with low consumer risks, the cosmetic product is of sub-standard quality, insufficient labelling information or warning of hazards to consumers.

Critical defect: a defect which is life threatening and requires immediate attention irrespective of company business hours. For example, the product has been deliberately tampered with or counterfeited or, the product has been labelled incorrectly.

Minor defect: a defect which does not have a significant impact on the use of the cosmetic product and is non-hazardous. For example, the absence of a label or packaging.

Reference documents:

11.279. Annex 1: Flow chart - Chemical waste categories

11.279. Annex 2: Flow chart - Types/ steps of waste management process

11.279. Annex 3: Flow Chart – In-process waste production

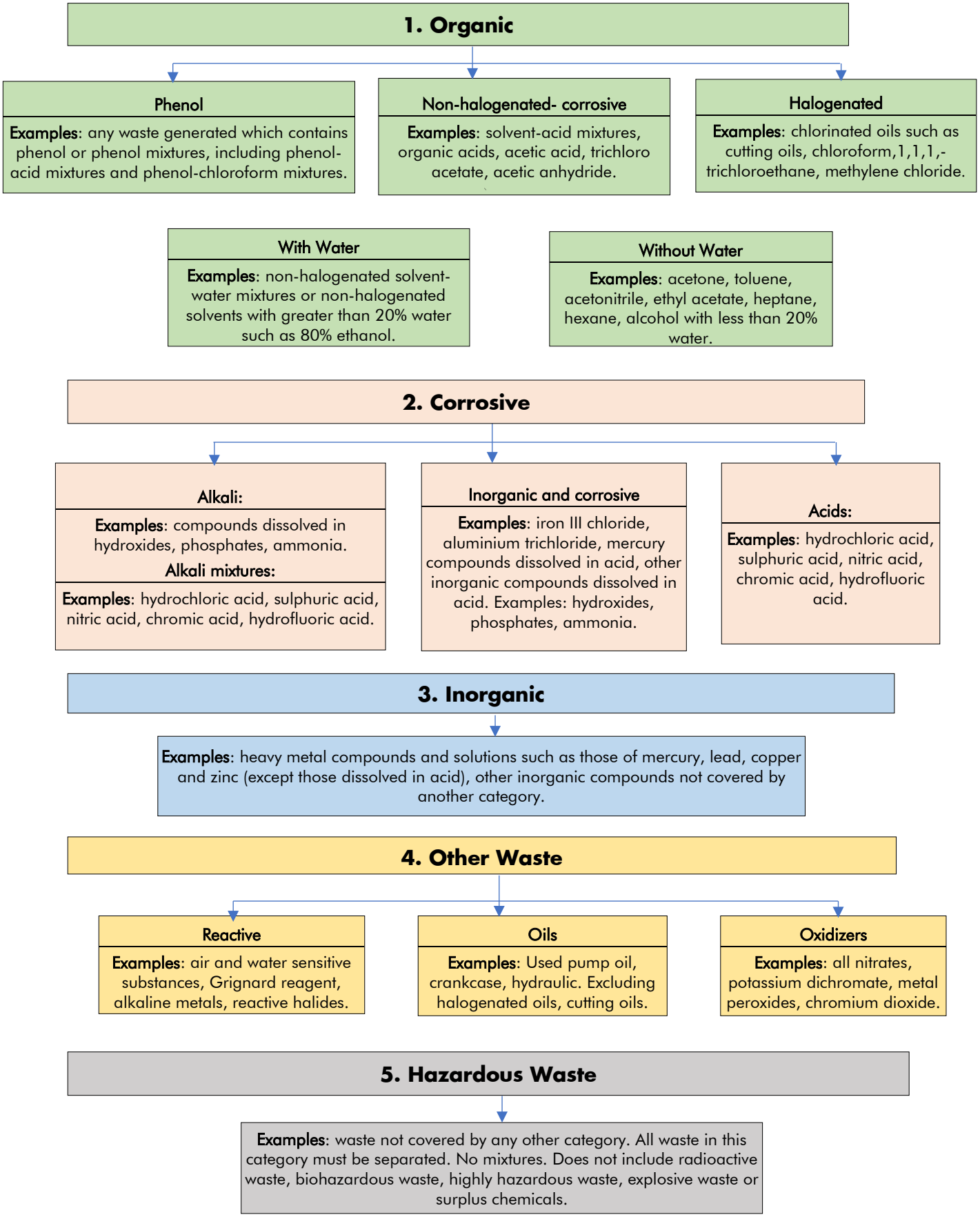
11.279. Annex 4: Form - Waste Identification sheet

11.279. Annex 5: Form - Hazardous waste disposal

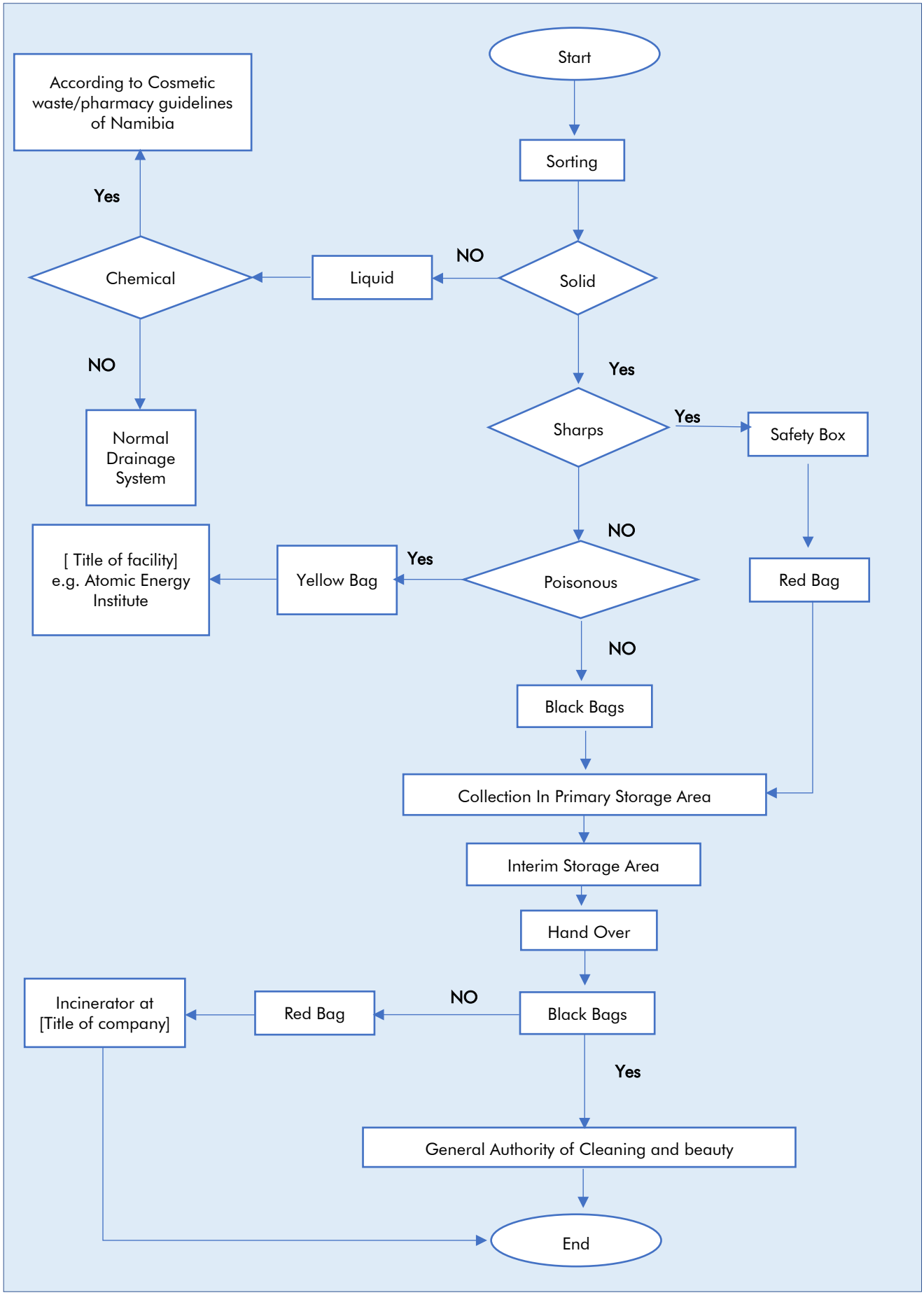
11.279. Annex 6: Form - Material Safety Data sheet

11.2. SOP 279 - Waste Management Plan

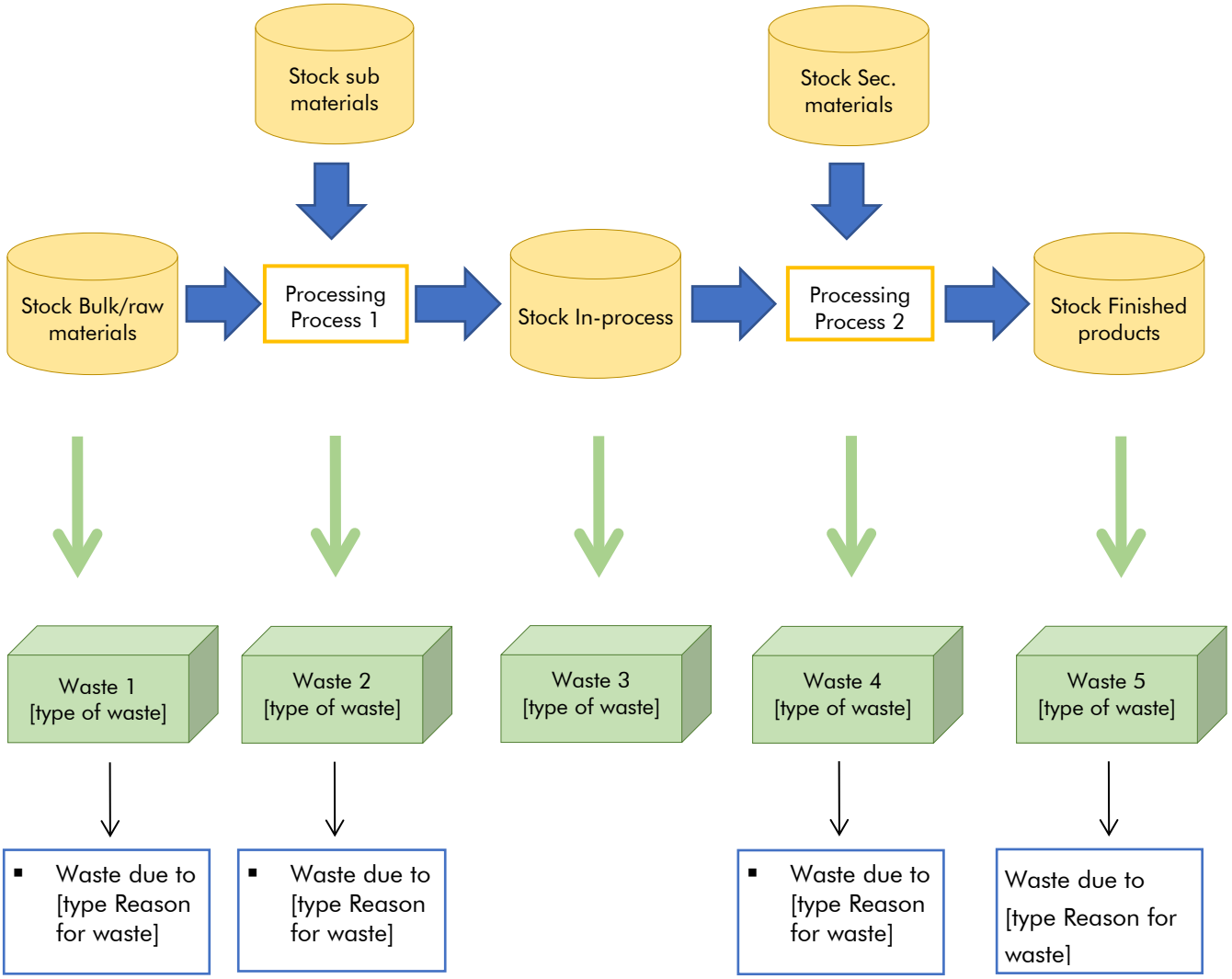
11.279. Annex 1: Flow chart - Chemical waste categories:



11.279. Annex 2: Flow chart - Types/ Steps of waste management process:



11.279. Annex 3: Flow chart – In-process waste production



11.279. Annex 4: Form - Waste identification sheet

Hazardous waste: Identification Form					
Format No.:					
Serial no.	Wastage from process:	Process name:	Waste unit:	Hazardous	Non-hazardous
Verified by:		Management representative signature:			

11.279. Annex 5: Form Hazardous waste disposal

Company name:				
Hazardous waste disposal form				
Name of substance and percentage	**Physical state (solid/liquid)**	**Description of container**	**Amount**	**Known hazards**
Name:		Signature:		
Date:		Area/dept:		

NB:

1. Radioactive waste is not allowed in the hazardous waste room. Any radioactive waste shall be reported to safety officer.
2. All substances must be labelled and identifiable, with name, type (organic/inorganic), state (solid/liquid) and quantity.

11.279 Annex 6: Material safety data sheet

Material Safety Data Sheet

Classified as hazardous/ non-hazardous		
	Issue Date:	Issued by:
Product:		
Name:		

1. Identification of the material and supplier	
Product name:	
Company name:	
Address:	
Emergency contact:	
Fax number:	
Email:	
Recommended use:	

Other Names	Name	Manufacturing Code

Other information:

2. Hazards identification	
Hazards:	
Classification:	
Risk Phrase(s):	
Safety phrase(s):	
Sensitization of product:	
Teratogenicity:	

3. Composition/information on ingredients	
Chemical:	
Characterisation:	
Information on composition:	

Ingredients	Name	Cas	Proportion	Hazard

4. first aid measures	
Inhalation:	
Ingestion:	
Skin:	
Eye:	
First aid facilities:	
Advice to doctor:	

5. Firefighting measures	
Firefighting measures:	
Suitable extinguishing media:	
Hazards from combustion products:	
Special protective equipment for fire fighters:	
Special hazards:	

6. Accidental release measures	
Spill and disposal:	Note:

7. Handling and storage	
Precautions for Safe Handling:	
Conditions for safe storage:	

8. Exposure control/personal protection	
National exposure standards:	
Engineering controls:	
Personal protective equipment:	

9. Physical and chemical properties	
Form:	
Appearance:	
Boiling point:	
Solubility in water:	
Specific gravity:	

pH Value:	
Evaporation:	
Rate:	
Volatile component:	
Flash point:	
10. Stability and reactivity	
Chemical stability:	
Conditions to avoid:	
Incompatible materials:	
Hazardous decomposition products:	
Hazardous polymerization:	
11. Ecological information	
Short summary of assessment of environmental impact:	
12. Disposal considerations	
Waste disposal:	
Container disposal:	
13. Toxicological information	
Inhalation:	
Ingestion:	
Skin:	
Eye:	
Chronic effects:	
Reproductive toxicity:	
Mutagenicity:	
Carcinogenicity:	
14. Transport information	
Transport information:	
Storage and transport:	

12

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 12: Subcontracting

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
Document No.:	NANCi-GMP-12- 00
Date of Issue:	30 November 2022

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Chapter 12 Subcontracting / services and contract manufacturing

Introduction

Contract manufacturing or subcontracting is defined whereby a company outsources services to another company to manufacture its products. The company awarding the contract is regarded as the company that mandates the service, while the company accepting the contract is regarded as the company which accepts the mandate. The company may be in the same country or another country. The stipulations of contract manufacturing must be clearly outlined, mutually consented, and controlled to prevent any misinterpretation which could affect the quality of work, production and final product. The contract should clearly stipulate the duties and responsibilities of each party. The contract is a binding document. It must follow the legislation of the respective country of the company awarding the contract, and the company which accepts it. In both cases, compliance with the GMP 22716 standard must be adhered to.

Subcontracting may help increase productivity; obtain expertise and specialised knowledge; and save costs. Where any activity in cosmetics production, storage, testing or shipping is subcontracted, the subcontractor has to implement the full GMP recommendations. The contract giver must ensure this is done.

Principles

The cosmetic manufacturer is required to ensure that the subcontracting service and contract manufacturing are well-established and clearly defined. Additionally, the company awarding the contract must clearly outline all requirements in the contract in accordance with the GMP regulations.

Scope

The contract manufacturing process covers various aspects in a cosmetic manufacturing industry including quality control or quality assurance, manufacturing operations, project management, finance and purchasing, product development, regulatory affairs, and legal affairs. The main focus of this chapter is how subcontracting applies to the company awarding the contract and the company accepting the contract within the cosmetic manufacturing company and testing laboratory.

Purpose

The first objective for the cosmetic manufacturer should be to ensure that all the requirements for contract manufacturing and the testing laboratory have been met. The second objective should be to ensure that the roles and responsibilities between the company awarding the contract and the company accepting the contract are defined and unambiguous.

Types of subcontracting

The cosmetic manufacturer must ensure that the types of subcontracts have been defined in terms of GMP requirements and contract requirements for the manufacturing and packaging of the following:

- Bulk and intermediary products
- Bulk products in primary packaging

- Tertiary packaging
- Sensorial analysis
- Chemical analysis
- Physical analysis
- Microbiological analysis
- Cleaning and sanitation where applicable
- Pest control
- Maintenance of premises

The company awarding the contract, hereinafter called the "contract giver"

A fundamental part of the quality system is the review and control of subcontracting services. The contract giver shall be in control of subcontracting processes and ensure that these are honoured. The contract giver must ensure that the subcontracting processes include the principles for quality risk management. The contract must include regular reviews based on the quality of the contract acceptor's implementation and identification strategies (see below). The contract giver is responsible for the upkeep of all documentation, assessments, and results subject to the manufacturing agreement. Another responsibility of the contract giver is to ensure that all products and materials received from the contract acceptor have been manufactured in compliance with GMP and the "marketing authorization".

The company accepting the contract, hereinafter called the "contract acceptor"

A qualified person from the company accepting the contract, may be assigned to confirm that the products and materials delivered to the contract giver are compliant with GMP standards and have been manufactured as per the manufacturing agreement. The contract acceptor is not allowed to make any changes or alterations which would affect the quality of the subcontracted products listed in the agreement, prior to the written consent from the contract giver. The contract acceptor must provide assurance that the company is capable of manufacturing the products listed in the agreement. This includes the availability of qualified staff, experience and resources.

Contract

For the contract to be valid, there should be authorised representatives from both parties. Furthermore, the contract must include a record of the products for contract manufacturing and the specifications for the finished product and instructions for the use of the product. The contract should also stipulate other details such as packing sizes, container specifications, guidelines for labelling including shipping labelling and storage conditions. Basically, the contract should include all the necessary data needed to carry out the tasks. A fundamental part of the contract is to define the responsibilities and duties of each of the respective parties.

Chapter 12. Subcontracting/services and contract manufacturing checklist

Chapter 12 Subcontracting/services and contract manufacturing checklist							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
	12.	Subcontracting / Services and Contract Manufacturing					
	12.1	Principle					
*277	12.1a	Are subcontracting / services and contract manufacturing defined in a written contract?					
278	12.1b	Are the requirements clearly defined in the contract by the contract giver?					
	12.2	Types of Subcontracting					
	12.2	Have the following been clearly defined in terms of contract requirements:					
279	12.2a	- manufacturing of intermediary bulk products?					
280	12.2b	- manufacturing of bulk products?					
281	12.2c	- packaging of bulk products in primary packaging?					
282	12.2d	- packaging in primary packaging = consumer unit?					
283	12.2e	- packaging in secondary packaging = trading unit?					
284	12.2f	- packaging in tertiary packaging = pallet unit?					
285	12.2g	- sensorial analysis?					
286	12.2h	- chemical analysis?					
287	12.2i	- physical analysis?					
288	12.2j	- microbiological analysis?					
289	12.2k	- cleaning / sanitisation, if necessary, including the premises?					
290	12.2l	- pest control?					
291	12.2m	- maintenance equipment?					
292	12.2n	- maintenance premises?					
	12.3	Contract Giver					
	12.3.1	The contract giver should assess whether the contract acceptor:					
293	12.3.1a	- is able to carry out the contracted operations?					
294	12.3.1b	- can carry out the contracted operations as agreed?					
295	12.3.1c	- is able to meet the Cosmetics GMP requirements (according to ISO 22716)?					
		The contract giver should assess whether the contract acceptor has the necessary resources to carry out the contract:					
296	12.3.1d	- suitable technical equipment?					

Chapter 12 Subcontracting/services and contract manufacturing checklist							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
297	12.3.1e	- suitable premises?					
298	12.3.1f	- suitable site?					
299	12.3.2	Has all the information required to carry out the operations been made available by the contract giver in detail? (examples: defined documents such as specifications, manufacturing rules etc)?					
	12.4	Contract Acceptor					
	12.4.1	Has the contract giver ensured that the contract acceptor can fulfil all requirements concerning the contract: i.e. does the contract acceptor:					
300	12.4.1a	- have the necessary resources?					
301	12.4.1b	- have the necessary experience?					
302	12.4.1c	- have the necessary experts/personnel?					
303	12.4.2a	- does the contract giver have the assurance that the contract acceptor will not pass on to a third party any of the work entrusted to him without the prior approval and consent of the contract giver?					
304	12.4.2b	- does the contract giver have the assurance that through the contract acceptor or any third parties involved, that all information concerning operations are made available, as represented in the contract / agreement?					
305	12.4.2c	- has the information, which has to be made available to the contract giver or third parties, been defined?					
306	12.4.3a	- are checks and audits by the contract giver to the contract acceptor contractually fixed?					
307	12.4.3b	- does the contract giver facilitate the contractually agreed checks and audits?					
308	12.4	- does the contract acceptor inform the contract giver of any planned changes that may affect the quality of the services or products? (Note: "Change Control")					
	12.4.1	Has the contract giver ensured that the contract acceptor can fulfil all requirements concerning the contract: i.e. does the contract acceptor:					
300	12.4.1a	- have the necessary resources?					
301	12.4.1b	- have the necessary experience?					
302	12.4.1c	- have the necessary experts/personnel?					
303	12.4.2a	- does the contract giver have the assurance that the contract acceptor will not pass on to a third party any of the work					

Chapter 12 Subcontracting/services and contract manufacturing checklist							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		entrusted to him without the prior approval and consent of the contract giver?					
304	12.4.2b	- does the contract giver have the assurance that through the contract acceptor or any third parties involved, that all information concerning operations are made available, as represented in the contract / agreement?					
305	12.4.2c	- has the information, which has to be made available to the contract giver or third parties, been defined?					
306	12.4.3a	- are checks and audits by the contract giver to the contract acceptor contractually fixed?					
307	12.4.3b	- does the contract giver facilitate the contractually agreed checks and audits?					
308	12.4	- does the contract acceptor inform the contract giver of any planned changes that may affect the quality of the services or products? (Note: "Change Control")					
	12.5	Contract					
309	12.5.1	Are the duties and responsibilities (de-limitation of obligations / responsibilities, "matrix") of the two parties defined in the contract?					
310	12.5.2	Does the contract acceptor keep or make available to the contract giver all data?					

Reference

IKW Cosmetics GMP based on ISO 22716

Website References

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 13th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/
Last viewed 13th September 2021

Pharma Change Control:https://www.fdanews.com/ext/resources/files/The_Food_And_Drug_Letter/2013/Pharma-Change-Control-Peither-ExecSeries.pdf
Last viewed 13th September 2021

12.286 SOP- Sample contract manufacturing agreement

Logo	**Standard format for SOP:** Sample contract manufacturing agreement Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

Scope:

This SOP applies to the contract giver and contract acceptor within the cosmetic manufacturing company and testing laboratory.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Responsibility:

Procedure:

1. A contract must be drawn up between the contract giver and contract acceptor and agreed upon by both parties.
2. Each representative must be duly authorised to accept/sign the contract.
3. Identify the scope of each task for the respective parties with regards to the following aspects:
   - Formula development
   - Prototype and acceptance evaluation
   - Safety and efficacy tests, where applicable
   - Packaging development
   - Raw material and packaging materials supply and testing
4. Include a list of the products for contract manufacturing.
5. Include specifications and instructions for finished products.

6. Include the following details.
    - Packing sizes
    - Packaging specifications and instructions
    - Labelling requirements and directions
    - Storage requirements
7. Both parties shall be held responsible for the quality of the products subject to the contract.
8. The contract giver shall be permitted to audit the contract acceptor/subcontractors and/or supervise the process of testing the contracted products during the period covered by the contract.
9. The contract acceptor shall not deviate or make any changes to the formulation and or process agreed upon by the parties for the manufacture or analysis of the product without the prior consent from the contract giver.
10. The contract should describe clearly who is responsible for purchasing materials, testing and releasing them, undertaking production and quality controls including the in-process control, and who takes responsibility for sampling and analysis.
11. Any records relevant to assessing the quality of the product or suspected defects must be accessible and specified in the defect/recall procedures of the contract giver.
12. The contract giver should be permitted to visit the facilities of the contract acceptor.
13. In the case of contract analysis, the contract acceptor should be aware that they are subject to inspection by the relevant authorities.

Sites for sample contracts:

[NB: listed below are some selected websites that offer free templates for contract/agreements and information which may be of use in relation to this chapter 12]

Sample No Disclosure Agreement: https://legaltemplates.net/form/non-disclosure-agreement/

Sample Legally Binding Provisions: https://www.lawinsider.com/clause/legally-binding

Sample Credit Worthiness: https://www.lawinsider.com/clause/creditworthiness

Sample Supply Agreement with T's and C's:
https://www.simpleformations.com/downloads/TermsandConditionsofSale.pdf

Reference documents:

13

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 13: Deviations

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
Document No.:	NANCi-GMP-13- 00
Date of Issue:	30 November 2022

NANCi
NAMIBIA NETWORK OF THE COSMETCIS INDUSTRY

Document origination

	Prepared by	Reviewed	Approved by
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Document change record

No.	Page	Rev.	Date	Details of change

Document revision record

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Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

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Chapter 13 Deviations

Introduction

According to GMP regulations, the word "deviations" is defined as a digression from an approved instruction or established standard. In other words, during the manufacturing process, a deviation may occur when a procedure, established standard or specification is in need of specified alterations due to unplanned or planned events. An important part of GMP compliance is being prepared for alterations or errors that may occur in production, so as to maintain the integrity and consistency of product quality. It is therefore necessary that the cosmetic manufacturer introduces established measures for both planned and unplanned deviations. All modifications with regards to deviations must be documented.

Planned deviations

Planned deviations are described and pre-approved deviations from the current operational document/system, covering a specified period of time or number of batches. Planned deviation is approved before execution. Planned deviations should be handled through the QA's Change Control procedures. All changes should be evaluated for product impact, significance, the need for requalification or revalidation. Changes are approved or rejected by QA. QA should insist that planned deviations are not the norm. Deviations should be unintentional, unplanned or unexpected.

Unplanned deviations

Unplanned deviations, also called "incidents". An incident can be defined as an unplanned or uncontrolled event where the designed systems or procedures, at any stage of manufacturing, packaging, testing, holding and storage of a drug or product, are disturbed for whatever reason.

Classifications

A deviation may be classified as "critical", "major" or "minor" depending on the magnitude of impact it may have on product quality. However, some deviations may have an impact on the quality of the product, whilst other deviations may have no or very little impact. Quality-impacting deviations are considered as occurrences or errors during execution of an activity which will affect the quality, purity and strength of the cosmetic product. Quality non-impacting deviations are errors or occurrences during execution of an activity which may have no impact on the quality, purity and strength of a cosmetic product.

Documentation

These include: Deviation reported in real time, timely notification to the QA (within 24 hours). Thorough root cause investigation. Timely investigation within 30 days. Corrective actions proposed and initiated or completed. Investigation closed. Implicated batch(es) released or rejected. Preventive actions initiated and closed.

The guidelines require that any deviation to the defined processing steps in production records should be documented. It may be useful to have an additional page in the production record to allow for recording of unexpected occurrences or deviations to the standard instructions. It is then the responsibility of the persons reviewing the completed production records (production) to decide which deviations are considered critical and require investigation. The quality unit checks the deviation records (not the full production/batch records).

The quality unit checks which procedure was followed, i.e. critical deviation records for impact on API quality and ensures that critical deviations are investigated. A critical deviation is defined as a variation to previously established critical parameters or a significant variation to standard operations which could affect the quality of the API or intermediate. Critical deviations should always be investigated, and corrective actions identified. Investigation and conclusions should be documented. Where deviations recur on a regular basis, the need to re-qualify equipment, retrain operators, redefine the process parameters or to implement other appropriate actions should be considered. Examples of deviation:

- Incorrect charging of raw materials
- Temperature, pressure, vacuum, parameters outside defined limits
- Operating instructions not correctly followed
- Breakdown of process equipment or failure of utilities
- Equipment out of calibration
- Production records not adequately completed
- Temporary alteration to defined production instructions
- In-process control limits not achieved
- Alternative production equipment used at short notice
- Extraneous contamination API and intermediates
- Any other unplanned event

Deviation investigations

The investigation should be conducted in an unbiased fashion. The main reason behind the deviation investigation is to identify the root cause of the deviation and implement suitable and effective corrective action. Recurring patterns that may be detected as a result of regular and consistent evaluation of the implicated system, could provide the company with useful data for further use, such as the need to implement or improve a particular training program. The investigation should involve at least 7 main steps:

1. Identifying the deviation
2. Documentation of the events
3. Immediate corrective action
4. Investigation of the root cause
5. Causal analysis
6. Corrective action
7. Effective evaluation

Corrective and preventive action

CAPA (Corrective and Preventive Action) is a deviation management program that focuses on the systematic investigation of discrepancies, adverse events or failures. If used correctly, the CAPA system will provide a means to prevent the deviation from recurring. (Systematic investigation of the deviation.) Corrective action is an action taken to eliminate the root cause and symptom of an existing deviation or non-conformity to prevent recurrence. This reactive action eliminates problems identified in products, services or processes and takes care of the immediate problem. Preventive action is an action taken to eliminate the potential causes of a non-conformity, defect or other undesirable situations which may occur. This is a proactive action which avoids deviations through planned activities. It also eliminates or reduces the recurrence of the problem.

Effectiveness evaluation

An effectiveness evaluation should be conducted to ensure that the corrective action has been completed and implemented as planned. This is important for the manufacturer to ensure that the corrective action is properly implemented. The evaluation period should be defined and set ahead of time. During evaluation, impacts and learning curves should be considered. Furthermore, the evaluation will determine the criteria for success, depending on the organisational SOP. The effectiveness evaluation should be initiated within a specified number of days after the implementation of the corrective action plan date.

Significance of documentation

Documentation is the backbone of the GMP compliance structure. If an action is not documented, then in essence it did not occur and does not exist. Thus in simple terms - "if it is not documented, it does not exist".

Principles

The company must have appropriate measures in place in the handling of deviations. The Corrective Actions and Preventive Actions plan is an excellent implementation tool. An investigation should be carried out to ensure that the CAPA plan is effective. The measures in place should provide sufficient data to conclude the appropriate and best solutions.

Scope

This chapter covers all matters related to the handling of deviations within the cosmetic production. The CAPA plan for deviations should be implemented in all situations or occurrences where any changes need to be made to any process or procedure in the manufacturing of a cosmetic product. In this chapter we address various components such as, planned and unplanned deviations, classifications of specific deviations, investigations and effectiveness evaluations of deviations, the CAPA plan, and the significance of documentation of all processes.

Purpose

Investigations into deviations is an essential component as failures may result in costs to the company. Moreover, failures can have an adverse health impact on the consumers if gone undetected. Another purpose for this chapter is to identify the cause of deviations and take corrective actions. Additionally, a good deviation system will allow the manufacturer to identify other similar situations and take preventive actions and facilitate continuous improvement. Correct measures concerning deviations is part of the GMP regulatory requirement.

Chapter 13 Deviations checklist

Chapter 13 Deviations checklist							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
311	13.1	Are measures in place which regulate the course of action or requirements in the event of deviations?					
312	13.1	Are sufficient data available to assist with the decision about a possible correction?					
313	13.2	Are the corrective measures implemented in such a way that a recurrence of the deviation/s is avoided?					

Reference

IKW Cosmetics GMP based on ISO 22716

Website References

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 13th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/
Last viewed 13th September 2021

Slideshare GMP handling of deviation: https://www.slideshare.net/DrAmsavelvel/gmp-training-handling-of-deviation
Last viewed 13th September 2021

Pharmaceutical guidelines SOP for CAPA: https://www.pharmaguideline.com/2012/07/sop-for-corrective-action-preventive-action-CAPA.html
Last viewed 13th September 2021

Pharmabeginers Annexure 8.0 Flowchart of CAPA handling: https://pharmabeginers.com/sop-for-corrective-and-preventive-action-capa/
Last viewed 13th September 2021

13.1. SOP 320 – Effectiveness evaluation and investigation of deviations

Logo	**Standard format for SOP:** Effectiveness evaluation and investigation of deviations Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To lay down the procedure…

Scope:

This SOP shall be applicable…

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

All Department Heads

Accountability:

Head Of Quality Assurance

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Where deviations have been detected, an investigation should provide the company with the following information:
   - Description of the occurrence
   - The time of occurrence
   - Where in the production process the deviation occurred
   - The frequency of the occurrence
   - How the deviation was discovered
   - Reason for occurrence
   - Possible solutions
2. The investigator shall provide a description of the deviation causing concern.

3. The investigator shall provide a report/s from the person/s involved in the discovery.
4. The investigator shall keep record of the time and date of the incident with respect to the deviation causing the concern.
5. The investigator shall provide a statement of the exact location of the incident with respect to the deviation causing the concern.
6. The investigator shall submit a report/data explaining how the deviation causing the concern was discovered.
7. The report reflects the frequency of the occurrence with respect to the deviation causing the concern.
8. With respect to the deviation causing the concern the investigator should include in the report:
    - Any environmental threats?
    - Is the working environment suitable?
    - Have any specific issues been detected with the flow of the process?
    - Does the facility pose problems?
    - Are there any issues related to equipment or materials being used?
    - Have clear instructions for the relevant procedure been provided?
    - Is there a lack of sufficient supervision?
9. The investigator checks the data base and documents to determine whether any faults can be found with procedure methods, SOPs, forms or task analysis. The investigator shall also conduct a comparative analysis between the steps performed by staff and the documented operation procedure or whether a process was recently changed.
10. The overall goal of the investigation shall be to determine how or why the deviation has occurred. On completion of the report, the investigator shall forward the findings along with the proposed solution(s) to the QA department for approval.
11. The investigator also states whether the deviation impacts other procedures, products or individuals, if applicable.
12. The investigator uses the information gathered to recommend any improvements that could be made to the CAPA plan and Deviations Investigation System.
13. Refer to "3. 320. Annex 1: Flow Chart: Immediate Corrections" below for a summary of immediate corrections with respect to products, equipment and processes in an average manufacturing company.
14. Effectiveness Evaluation:
15. Following the development of the CAPA plan, the manufacturer shall ensure that an investigation is conducted to verify the effectiveness of the CAPA plan.
16. Based on the effectiveness evaluation, the manufacturer shall ensure the CAPA is accurately implemented by staff.
17. The evaluation period shall be defined and set ahead of time.
18. During the evaluation, impacts and learning curves shall be taken into consideration.
19. The data from the evaluation shall be utilised to develop a criteria for success, depending in the organisational SOP.
20. The effectiveness evaluation shall be initiated within a specified number of days after the implementation of the corrective action plan date.

Definitions:

CAPA: Corrective Actions and Preventive Actions: It is a specified system that will be used by the company in the event of deviations from the usual procedure.

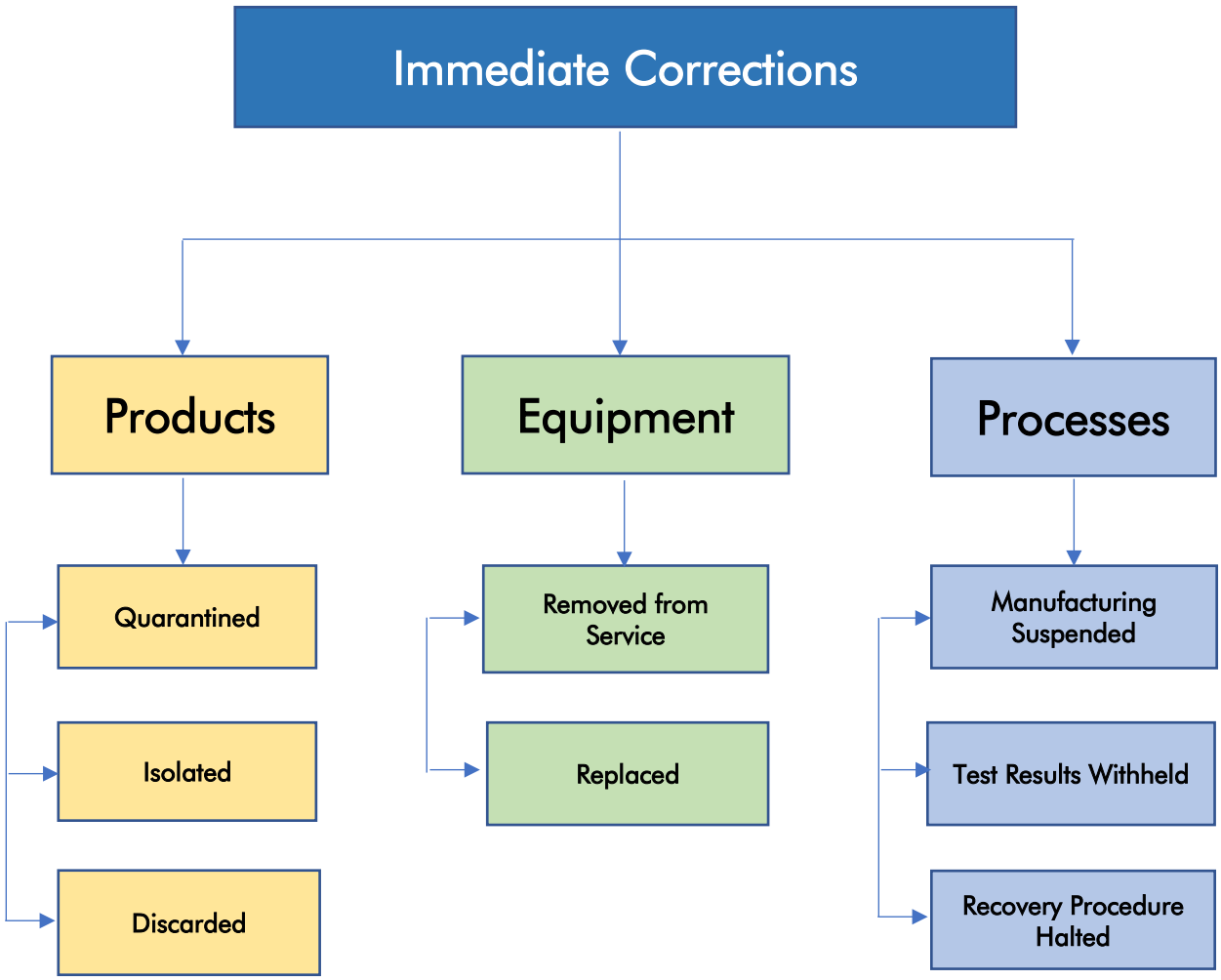
Reference documents:

14.332. Annex 1: Form - Investigation records

13.320. Annex 1: Flow Chart: Immediate Corrections

15.0 SOP 338 - Change control Procedures

13.320. Annex 1: Flow Chart: Immediate Corrections



13.2. SOP 322 – Corrective actions and preventive actions (CAPA)

Logo	**Standard format for SOP:** Corrective actions and preventive actions (CAPA) Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To introduce the procedure to be followed for the administration of Corrective and Preventive Actions (CAPA) including tracking and reporting of the status of CAPA.

Scope:

This SOP shall be applicable for tracking and to follow up open CAPA as well as verifying completed CAPA.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

All Department Heads

Accountability:

Head Of Quality Assurance

Materials and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Upon discovery of a deviation, the CAPA form annex 1 is completed and is regarded as a tracking document of the CAPA procedure from the Source Document (SD).
2. **Implementation of CAPA:**
   - 2.1. The decision to implement CAPA shall be taken by the Head of Department, prior to the issuance of the CAPA form Annex 1.
   - 2.2. The QA shall be responsible for the maintenance and record keeping of all CAPA forms.
   - 2.3. The form shall include the following information:
     - Name of department
     - Initiation date of CAPA
     - Proposed date of completion

- Root analysis and description (this should be based on the SD)
- CAPA description and detail from the source document
- Name and signature of Department Head
- Date

2.4. Once the Department Head has completed the form, it shall be forwarded to the QA.

2.5. The appointed QA member enters a reference number on the CAPA form as well as any applicable entries in the CAPA logbook Annex 2.

2.6. The appointed QA member thereafter forwards the document(s) to the department concerned.

3. Numbering of CAPA:

- Each case shall be numbered in sequence for each department
- The numbering sequence shall be as follows: CAPA/department three letter code/ form number, starting at 001 for every department/the last two digits of the current year. For e.g., CAPA/PCK/009/21 this represents the 9th CAPA from the packaging department in the year 2021.

4. Certification and verification on closure of CAPA:

4.1. After CAPA has been carried out, the Head of Department certifies that it has been completed and implemented.

4.2. The QA shall be held responsible for verifying that the CAPA has been completed and implemented and shall ensure that supporting documents have been reviewed.

4.3. Should there be any proposed alterations or adjustments, it shall be conducted through" SOP 338 - Change Control Procedures".

4.4. All Deviations, and Discrepancy Reports giving rise to CAPA shall be addressed through the CAPA form.

4.5. CAPA shall be implemented for the following:

- Building renovations
- Major alterations to quality system
- Capital purchase requisites

4.6. Each CAPA is kept on record. The records are regularly maintained and kept up to date.

4.7. Both the Head of Department and QA receive a copy of the completed CAPA. A copy of the CAPA is affixed to the SD.

4.8. All CAPA information is collected by the Head of Department and summarized.

4.9. The summarised version of the CAPA is presented to management at the quarterly Management Review Meeting.

4.10. All data in connection with CAPA, based on internal and external audits as well as regulatory inspections, shall be deemed confidential and shall only be accessible after authorization by the Senior Vice President for supervisory review.

5. **A Corrective Action Plan shall be implemented following these instructions:**

5.1. Develop the changes to relevant SOPs

5.2. Include the process changes

5.3. Training or re-training

5.4. Implementation of automation or new equipment

5.5. Decide on the implementation time frame

5.6. Determine staff involved in carrying out the corrective action (CA)

Definitions:

CAPA: Corrective Actions and Preventive Actions: It is a specified system that will be used by the company in the event of deviations from the usual procedure.

Reference documents:

13.322. Annex 1: Flow Chart - CAPA Handling

15.0 SOP 338 - Change control Procedures

14

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 14: Complaints and Recalls

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
Issue No.:	01
Document No.:	NANCi-GMP-14- 00
Date of Issue:	30 November 2022

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Document origination

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Document change record

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Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

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Chapter 14. Complaints and Recalls

Introduction

This chapter deals with the establishment of a program for dealing with product complaints in respect of quality, safety and standard. In addition to a system for the handling of product complaints, a cosmetic company needs to have a well-developed product recall system which is in alignment with the GMP guidelines. Product recall is defined as the withdrawal or removal of a product from all distribution outlets. Usually, the cosmetic manufacturer will recall a product due to critical quality defects or due to reports of severe side effects with severe health risks to consumers. If the distributed product is found to pose significant hazards to consumers, a safety alert must be communicated to the public through platforms like newspapers, radio or television. When a product is recalled, it usually implies that the product was removed for reworking, although in most cases a recalled product cannot be renewed through rework. When a product is listed under "withdrawal" the product was removed for other reasons e.g., as a marketing strategy.

Principle

The cosmetic manufacturer ensures that an investigation is conducted concerning all product complaints and any other reports regarding defective products. The investigation must be carried out in writing. A product recall must be conducted in accordance with GMP guidelines and corrective and preventative measures.

Purpose

The purpose of this chapter is to establish a system for handling product complaints and product recalls. This will assist in identifying the fundamental concerns of potentially defective products known or otherwise. The establishment and incorporation of these system will act as a mechanism to protect human and animal health.

Scope

The chapter covers key aspects pertaining to product complaints, product recalls and other reports regarding products suspected to be defective.

Product complaints

The cosmetic manufacturer appoints a qualified individual to handle product complaints. This individual is issued with the authority to make decisions concerning actions to be taken to resolve the issue. A written procedure detailing the measures to be taken must be available. The complaint must be addressed within a reasonable time span with appropriate follow up actions. In the case where a batch or product is found or suspected to be defective, the appointed individual should examine whether any other batches have also been affected. The manufacturer must be notified of all complaints and remedial actions prior to initiation. All complaints and remedial action must be documented.

Product recall

A product may be recalled for a variety of reasons, e.g., when the recall is considered mandatory or when directed by the National Regulatory Authorities. The types of voluntary recalls include customer complaint, discovery of quality and safety failure after release, because of stability testing, tampering or due to adverse reporting. The cosmetic manufacturer should appoint, for the purpose of recall issues, an individual who will

act independently from the marketing department. The appointed individual has access to all distribution records. There must be a suitable storage area for recalled goods. Where a mandatory recall occurs, the manufacturer ensures that the authorities in all countries to which the product was distributed have been informed. If necessary, public warnings are issued to notify customers. Based on the level of risk involved, the class of risk is defined by the Product Recall Committee. The Product Recall Committee is responsible for handling all issues concerning recalls with the required urgency.

Chapter 14 Complaints and recalls checklist

Chapter 14 Complaints and recalls checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	14.	**Complaints and recalls**					
	14.1	**Principle**					
313	14.1.1	Are all complaints that fall within the scope of these guidelines and are communicated to the plants applicable, reviewed, investigated and followed up?					
314	14.1.2a	In the event of a product recall, are the correct steps and decisions taken in order to complete the recall within the scope of these GMP guidelines?					
315	14.1.2b	When a decision has been taken on a product recall, are corresponding corrective and preventive measures initiated?					
316	14.1.3	Is the process of dealing with complaints laid down in the agreement between the company awarding the contract and the company accepting it?					
	14.2	**Product Complaints**					
317	14.2.1	Are complaints centralised by authorised personnel?					
318		In the event of any complaints concerning a product defect, are the original details and follow- up information combined?					
319	14.2.2	Have corresponding follow-up measures been performed for the batch of the recalled product and have these been documented?					
	14.2.3	**Do the complaint investigations and follow-up include:**					
320	14.2.3a	- steps to prevent recurrence of the defect?					
321	14.2.3b	- checking other batches in order to determine whether they are also affected?					
322 *	14.2.4	Are complaints reviewed periodically to check for trends or recurrence of a defect on a precautionary basis?					
	14.3	**Product Recalls**					
323	14.3.1	Is the recall process co-ordinated by authorised personnel?					
324	14.3.2	Are product recall operations initiated promptly and in a timely manner?					
325	14.3.3	Are the appropriate authorities notified of recalls which could have an impact on consumer safety?					
326	14.3.4	Are recalled products stored separately in a secure area while awaiting a decision?					
327*	14.3.5	Is the product recall process evaluated periodically?					

Chapter 14 Complaints and recalls checklist							
		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	

Reference

IKW Cosmetics GMP based on ISO 22716

Website References

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

Last viewed 13th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

Last viewed 13th September 2021

Pharmaceutical guidelines Handling of Market Complaints in Pharmaceuticals: https://www.pharmaguideline.com/2011/08/sop-for-handling-of-market-complaints.html

Last viewed 13th September 2021

Pharmaceutical guidelines SOP for Product recall: https://www.pharmaguideline.com/2012/07/sop-for-product-recall.html

Last viewed 13th September 2021

14.332. SOP - Complaint handling procedure

Logo	**Standard format for SOP:** Complaint handling procedure Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the procedure for handling all complaints and other information pertaining to potentially defective products, received from the customer or any other external or internal party, with any of the company's marketed products.

Scope:

This SOP is applicable to the cosmetic manufacturer and the person assigned to the task of handling complaints. This SOP covers all aspects related to complaints and any reports regarding products suspected to be defective.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The manufacturer shall appoint a responsible individual(s) to be held accountable for the following task:

- Investigate product complaints
- Identify and resolve product defects
- Review problematic issues

Procedure:

1. The cosmetic manufacturer appoints a responsible person to handle all complaints.
2. If recall management is subcontracted, the contract giver and acceptor agree on the process for managing recalls according to the GMP recommendations.
3. The appointed person is given the authority to make decisions with regards to remedial action in connection with the complaint.
4. The complaint may be written or verbal and response to it should be within a reasonable time span.
5. All written and/or verbal comments concerning the complaint are recorded by the appointed person.
6. The person in charge immediately initiates an investigation addressing the complaint.

7. The person in charge documents all findings from the investigation. The person in charge keeps a record of these findings (Investigation Records Form).
8. Remedial Actions:
   8.1. The person in charge of complaints is responsible for taking decisions subject to remedial actions, based on the outcome of the investigation.
   8.2. Should the person in charge of complaints decide to make a recall, the procedures stated in Product Recall SOP shall be applied.
   8.3. Further steps to prevent product defects shall be the responsibility of the company management.
9. Response to complaints:
   9.1. Only the person appointed to handle complaints for the company responds to complaints received.
   9.2. The person assigned to handle complaints responds to complainants immediately and thereafter notifies the manufacturer immediately.
   9.3. If the investigation results are communicated telephonically the date and information forwarded is noted down.
10. Complaint Decision:
   10.1. The complaint decision is evaluated as either justified or not justified.
      - The complaint is considered "justified" if a failure in the quality system was detected. If the complaint is justified, actions must be taken to prevent reoccurrence. These actions must be documented. The process of the ongoing actions must be followed. Where necessary the product may be subjected to recall.
      - If the complaint is not justified, the complainant shall be advised based upon the findings, including the relevant marketing response.
11. Defects are classified as either critical, major or minor and classified as either technical or medical.
12. Trend review:
    - The person in charge of complaints conducts a regular review of the trends associated with the complaints received by the cosmetic company within a set time period.
    - Trends in product complaints are analysed to establish improved corrective and preventative procedures.
    - The person in charge of complaints observes any recurring problems/complaints.
    - The person in charge of complaints observes any potential recall or withdrawal.
    - Any serious quality issues are reported to the appropriate authority.
13. Each individual complaint is documented and filed.
14. The person in charge of complaints will prepare a final written report on the product complaint.
15. For product safety reasons, the relevant authority is notified of the recall.

Definitions:

Major defect: non-conformity of a product which is evident to the consumer and is non-hazardous or barely hazardous. For example, microbiological contamination of products with low consumer risks, the cosmetic product is of sub-standard quality, insufficient labelling information or warning of hazards to consumers.

Critical defect: a defect which is life threatening and requires immediate attention irrespective of company business hours. For example, the product has been deliberately tampered with or counterfeited or, the product has been labelled incorrectly.

Minor defect: a defect which does not have a significant impact on the use of the cosmetic product and is non-hazardous. For example, the absence of a label or packaging.

Reference documents:

14.322. Annex 1: Form - Investigation records

14.322. Annex 2: Form - Complaint Investigation Sheet

14.322. Annex 3: Form - Complaint form #2

14.3. SOP 327- Product Recall Procedure

14.322. Annex 1: Form - Investigation records

Company Title:							
Complaint Investigation Record							
Product name:	Active substance:	Product Type:	Batch number:	Name of complainant:	Nature of complaint:	Staff interviewed:	Investigated records and details

Staff interviewed:	Results of investigation		Actions taken:		Date investigation started:	Date investigation ended:	Signed-off upon completion:
	Justified	Not justified					

14.322. Annex 2: Form - Complaint investigation sheet

Company name:		
Complaint Investigation Sheet		
Product name:	**Type of product:**	**Product code:**
Date:	Time:	
Officer involved:	Place of occurrence:	
Complainant name:	Complainant address:	
Date of complaint:	Time of complaint:	
Report on what occurred on the date in question (be specific):		
Signature:		
Assigned complaint number:		

14.322. Annex 3: Form - Complaint form #2

Company name:		
Nature of the complaint		
Date:		
Complaint:		
Originator of the complaint and title:		
Distribution contact person and title:		
Method of notification:		
Name:	Phone number:	
Date shipped:	Invoice number:	
Product name:	Expiry date:	Control number:
Total quantity shipped:		
Reason for complaint return request:		
Complaint number:	Product:	
Evaluation of complaints: 1. Physical characteristics 2. Sign of deterioration 3. Other observation(s)		
Signature:	**Date:**	

14.327. SOP - Product recall procedure

Logo	**Standard format for SOP:** Product recall procedure Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To establish the procedure for prompt and efficient recall of products known or suspected to be defective, from the market.

Scope:

This SOP applies to all types of recalls either initiated by XXX company voluntarily or by the National Regulatory Authority.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The designated responsible person shall ensure that the product recall is executed effectively and promptly upon receipt of the recall instruction from the Managing Director or Recall Order from any Regulatory Authority.

Procedure:

1. Recall can be initiated in the following situations:
   - 1.1. A recall instruction from the Managing Director in response to a complaint received, where a serious product quality problem was detected in the product and/or the product was found to have adverse reactions in consumers.
   - 1.2. A recall instruction decision from the Managing Director in response to any in-house detected defective products.
   - 1.3. A recall order from any Regulatory Authority - the designated responsible person consults the Regulatory Authority and management to determine the extent and nature of recall.
2. Recalls are classified into the following categories:

Class 1 Recall

Initiated when the product defect poses a life-threatening situation to users. Some examples of defects that will result in Class 1 recall is contamination with toxic substances and products with major labelling errors.

Such recalls are given the highest urgency and reported to NRAs immediately.

Class 2 Recall

3. Initiated when the problem or defect is unlikely to cause serious harm to users. Some examples of defects that will result in Class 2 recalls include products with minor labelling errors or products which fail to meet product specifications or pharmacopoeia standards but are likely to cause minimal hazards to users.
4. The designated responsible person informs the sales/marketing department or inventory control section to generate the distribution records of the affected batch.
5. All sales of defective products will be ceased immediately, and the designated responsible person instructs the storekeeper to immediately remove any stock of the affected batch from the warehouse and quarantine the goods at a designated quarantine area.
6. All recipients of the affected product are notified of the nature of the recall by telephone. For end-user recall, mass media communication should be considered.
7. A recall letter is prepared by the designated responsible person and sent to all recipients of the affected batch listed in the distribution record, to inform them that a recall operation has been activated, and to stop selling and remove the affected product from the racks with immediate effect.
8. The National Regulatory Authority and Overseas Regulatory Authorities to which the affected product batch was exported are notified of the recall in situations 1.1 and 1.2. The Officer of the National Regulatory Authority is informed within 24 hours from the receipt of the defective reports.
9. The designated responsible person instructs the delivery personnel to collect the recalled product from the market, the pharmacies, hospitals, distributors or any other outlets as stated in the distribution record.
10. All recalled goods collected from the market are clearly identified and stored in the designated secure area while awaiting management's or the National Regulatory Authority's decision.
11. The progress of the recall process is recorded, and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.
12. The records are filed in the Recall file kept by the Admin or QC Department.
13. Mock recalls are carried out on a yearly basis to assess the effectiveness of the recall system which is in place. Any irregularities found in the system during the mock recall shall be addressed so that the operation can be activated immediately and promptly during an actual recall.

Definitions:

Product recall: a procedure for removal of a product from the market or extraction from all links of distribution. A product is usually removed or withdrawn if major quality defects are detected or serious adverse cosmetics responses reported which may result in health risks to consumers after distribution of the product.

Withdrawal: The extraction of a product from sale or use by reasons unrelated or not attributed to the quality and safety of the product, for example withdrawal due to marketing strategy or for packaging reasons.

Recall for Product Correction: When a product is removed for rework purposes.

Reference documents:

14.327. Annex 1: Form – Product Recall

14.327. Annex 2: Form - Product Release sheet

13.2. SOP 332 - Complaint Handling Procedure

14.327. Annex 1: Form – Product recall

Product recall record form	
Form no.:	Revision no.:
Recall no.:	
Product particulars	
Name of product to be recalled:	
Strength of product:	Dosage form:
Pack size:	Batch number:
Date of manufacture:	Expiry date:
Quantity manufactured and released for distribution:	
Name and address of manufacturer:	
Country of manufacture:	
Date of recall:	Date of completion of recall:

Details of product defect
Date of occurrence of defect:
Nature of defect:
Cause of defect:
Number of occurrences of similar defects:
Results of test or investigations:
Assessment of whether recall is likely to affect other batches if same product(s) or other products manufactured by same plant:
Class and level of recall:
Proposed corrective action (if any):

Reconciliation of product recall	
1. Quantity manufactured:	
2. Quantity sold/supplied in [country/town] attach copy of sales/distribution records:	
3. Quantity exported (attach copy of distribution records):	
4. Quantity of remaining stock in the warehouse:	
5. Total quantity recovered from recall:	
6. Quantity that cannot be recalled:	
7. Action taken on recalled stock (attach proof of action taken):	
Evaluation of recall: (whether recall is complete, explanation on any discrepancy):	
Follow-up actions taken:	
Name of person in charge of recall:	
Signature:	Date:

14.337. Annex 2: Form - Product release sheet

Product release form			
The following product is available for release to market supply			
Product:			
Batch no.		Batch size:	
Mfg. date:		Expiry date:	
Packing details:		Number of intact:	
Loose pack:		Number of loose packed:	
Total qty. released		Total number of packed released:	
Reference number:			
Prepared by:	Checked by:	Released by:	
Format number:			

15

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

Title: GMP Chapter 15: Change Control

Standard:	ISO EN 22716: 2007 COSMETICS GMP
Revision No.:	00
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Document origination

	Prepared by	Reviewed	Approved by
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Designation:			
Signature:			

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No.:	Document change number:	Author:	Effective date:	Remarks:

Document approval and implementation

	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

Table of Contents

Chapter 15. Change control

Introduction

To enable a company to produce and market a cosmetic product internationally, it must acquire approval from the relevant governing agency to ensure that it complies with quality, efficacy and safety regulations. However, to achieve GMP compliance, the company must adhere to various requirements. The manufacturing company must possess documented instructions for all manufacturing and quality control procedures. The company must specify the materials required and state the main conditions needed for a reproducible quality of product. Change control is therefore a key component in the Quality Assurance System. It is essential to have written procedures in place that define actions to be taken in the case of any recommended changes to a product ingredient, production equipment, production area or site, method of production or testing, or any variations which may impact product quality and/or production quality.

Principle

The main principle behind change control is to ensure that the company adheres to the GMP requirements throughout the entire process of the cosmetic production procedure. The company should have written specifications for materials and directions for all manufacturing procedures on record. The change control system should be updated regularly, and each change control should be recorded. Occasionally, manufacturers may need to redefine, modify, enhance or cancel certain data in procedures. This is the basis of "change control". A key element of the change control system is to ensure that each "change" has been reviewed, approved and authorised, if it is to be kept in the system.

Purpose

This chapter describes the process to request and manage the change control system in a cosmetic manufacturing company. The change control system applies to all relevant areas including policies, processes and systems. The establishment of a change control system will provide an efficient means for handling requested changes and reported setbacks. It will ensure that the relevant stakeholders of the project team have the necessary information regarding requested changes. Finally, it will minimise ambiguity around the existence, state and outcome of a requested change.

Scope

This chapter is applicable to all areas of cosmetic production including premises, personnel, material and product specifications and production processes and deals with requested changes, grading of changes, the Change Control Committee, deviations and change control documentation procedures.

Grading the changes

Changes should be graded or categorised according to the frequency of the change and the area under consideration. For example, many companies would have a special change procedure in place for changes to printed packaging material (directions for use, boxing/wrapping and labels). This is because these changes occur often, and the process sequence can simply be standardised to coordinate with the change. The flowchart below provides a simple outline for grading classifications. It should be remembered that the chart only serves as an example and may be extended or changed according to the requirements of the individual

company. The grading chart provided should not be used as a substitute for individual evaluation of the change. Some case changes may not coincide with a prefabricated chart but may rely on knowledge and experience.

Deviations

A deviation is regarded as an adverse and unprepared variation from a requirement. The procedure for handling a deviation differs significantly to that of change control. It is important to understand that a deviation should not be regarded as change since it does not line up with the aim and procedure of change control. In chapter 13, a special procedure for handling deviations has been formulated.

Change control committee

The "Change Control Committee" (CCC) is a team of selected individuals assigned to evaluate changes, agree, and finalise the required measures to be taken concerning change control, communicate and manage the measures to the relevant departments and issue final authorisation. Members of the CCC may be the QA Head (usually the chairman of the team), Production Head, Sales Head, Head of Regulatory Affairs, and the Information Representative. Other departments may also be involved. The CCC only addresses a change control that may have an influence on the attributes (quality/characteristic) of a GMP-relevant system, facility, equipment, material/product, or a procedure/process. A fundamental factor which the CCC should address is to take a decision on which changes to handle first. The CCC may not be capable of addressing all change cases in the company due to capacity reasons. Therefore, only the changes requiring control should be processed by the committee. These are changes that have an impact on the regulatory status and necessitate reporting or permission processes. Changes that potentially affect the features of a GMP-relevant system, facility, instrument, material/product or procedure/process are also included. The CCC should also be involved in modifications where the execution is lengthy and necessitates coordination. Furthermore, all changes concerning grading or implementation, and which may be ambiguous or disputed should be addressed by the committee.

Not all change control methods necessitate the convening of a meeting. Meetings may require the presence of numerous essential function heads in person. Traditional paper-based circulation procedures (serial or parallel), e-mail agreements or shared access to Intranet-based forms are all worth considering in circumstances where simple decisions are required.

Change requests can only be considered by the committee if they have been allocated. The high level of involvement is passed on to the rest of the company's employees. If no one assesses a key change and no documented change control mechanism is implemented, serious quality issues can arise. When a corporation implements a change management programme, the committee can assess the system's effectiveness using readily available data as follows:

- Yearly total of completed change procedures
- The number of procedures that were prematurely discontinued due to procedural deviations
- Type of change/work expense
- Procedure time: from application to completion
- Total number of change procedures/number of grading difficulties
- Annual number of OOS findings
- Annual number of internal and external complaints
- Issues with stability/batch reviews/recalls

The Change Management Programme can assess the system's functionality by looking at the effort and speed of change operations, or by looking at the deviations. The knowledge and experience of the personnel involved determines the effectiveness of a change control programme. As a result, ongoing training in change management methods is critical. To ensure speedy implementation, committees should arrange for simple documentation procedures and communication sequences.

Deviations are unintended and usually undesirable changes. Internal and external complaints, stability issues and batch recalls are examples of how they can manifest themselves. If they occur, it could mean that the change management programme has failed. It is possible that a significant process parameter or material specification modification was unnoticed, or that a detrimental trend in the development of process data went unnoticed.

Documentation

To obtain GMP compliance, it is important to have written documentation of a change control system in place, to regulate the classification of changes with respect to the area the SOP applies to. The system of change approval and initiation, the way the change request will be handled, who oversees grading, execution and monitoring the change control processes are to be considered. The SOP should also clarify how the required measures for conducting the change will be determined and who will compile the required measures. Other important factors to document include details on the format, content and archiving methods of the change control cases. In addition, responsibilities and authorities of relevant individuals should be clearly outlined, and there should be special regulations in place for urgent changes. The records may be kept on paper or in electronic format. Keep in mind that raw (crude?) data and other related documents must be available while keeping these records.

Change requests

Any changes which necessitate control are recorded in the Change Request Form. In this request form, the applicant issuing the change provides an evaluation and recommends a grade for the change. The form is submitted to the CCC for approval and may be authorised or rejected. The document should specify a time parameter and measure for implementing the change. The change procedure documentation should show that the change was reviewed (risk analysis) and that the subsequent defined steps were implemented according to plan. Timing and contents should be coordinated before the change is being conducted. For the coordination of complicated changes, a clear description of the individual measures for a project plan is helpful. The “change control” SOP portrays clear instructions of the procedure of change control and includes appropriate documentation for the change procedure.

Chapter 15 Change control checklist

Chapter 15 Change control checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	15.	**Change Control**					
*338	15a	Has a process been defined for changes (equipment, material, process etc) which could affect the quality of the product?					
339	15b	Are changes performed by authorised personnel?					
340	15c	Are the changes authorised and completed on the basis of sufficient data?					
341	15d	Are the changes documented?					

Reference:

IKW Cosmetics GMP based on ISO 22716

Website References:

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

Last viewed 13th September 2021

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

Last viewed 13th September 2021

Pharma Change Control: https://www.fdanews.com/ext/resources/files/The_Food_And_Drug_Letter/2013/Pharma-Change-Control-Peither-ExecSeries.pdf

Last viewed 15th September 2021

15.0. SOP 338 (a) - Change control procedures

Logo	**Standard format for SOP:** Change control procedures Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

1. Purpose (of the instruction):

Internal requirements are specified in order to comply with the legal cosmetic product provisions and the GMP Guideline, as well as to ensure that the quality of the cosmetic product complies with the approval and is reproducible. These requirements cover the entire manufacturing process and the quality control for a cosmetic product, including the materials and equipment/apparatus used.

The purpose of this instruction is to make certain that the quality of the cosmetic product, the safety of equipment/apparatus, the safety of procedures/process and conformity with the relevant application files for marketing authorisation are maintained in the event of changes to these requirements.

2. Definitions and Abbreviations:

Change: planned deviation (extension, replacement, removal, addition) as part of a requirement.

Change control: a system with which qualified representatives from corresponding departments evaluate current or planned changes with regards to a specific status. The aim is to establish precautions that are necessary to prove and document compliance with the specific status.

Applicant: person who is initiating a change with a change request.

Apparatus: the object used for technical processes.

Minor change: Changes to apparatus, material/product or procedure/process which may not affect critical attributes of a system. Impairment of the product quality/process reliability is not likely. Minor changes may require notification to the regulatory or supervisory authorities.

CCC: Change Control Committee.

Major change: change which cannot be classified as a minor change or which may affect the critical attributes of a system, facility, apparatus, material/product or procedure/process. Impairment of the product quality/process reliability is likely. Major changes may require authorisation by the relevant regulatory or supervisory authorities and/or prior revalidation or requalification.

Process: set of interrelated methods and activities which convert an input into results.

System: established way of carrying out an activity.

Trial: preliminary, temporary changes which are permanently established or revoked after a trial period.

3. Responsibility:

3.1. Responsibilities for the established procedures:

3.1.1. The legal responsibility of cosmetics concerning planning, implementation and authorisation of changes is borne by the Head of Production, the Head of Quality Control or QA, (however it is important to clearly differentiate the tasks of QA and QC), the sales manager and the information representatives for their relevant area. They must ensure that:

- the qualification status of the rooms and facilities that are affected by a change is maintained or that a re-qualification is implemented.
- The validation status of the processes/procedures that are affected by a change is maintained or that a re-validation is implemented.
- Changes to manufacturing, analysis and labelling of a cosmetic product are based on a valid approval/registration.
- The documentation required for the change is compiled or updated.

3.1.2. The organisational processing and documentation of change control procedures is conferred to the Change Control Committee (CCC). The CCC comprises those in the roles mentioned above and the Head of Regulatory Affairs and the QA representative. Other heads of departments or experts may be called in, if requested by one of the members. The committee has the following tasks:

- Risk evaluation of the change request
- Authorisation or rejection of the application
- Establishing and scheduling necessary measures

3.1.3. The chairman of the CCC is the QA representative. He has the following tasks:

- Calling the CCC meetings and taking minutes
- Coordination of the circulation procedure
- Maintenance of the database of change control procedures
- Formal control of the change requests
- Monitoring compliance with deadlines
- Archiving the completed change requests

3.2. Responsibility for the revision of this instruction:

- The QA representative is responsible for checking this instruction regularly to make sure it is up to date and for revising it if necessary. He must release a new version at least every two years.

4. Procedure:

4.1. Basic principles

4.1.1. GMP or approval-relevant changes must only be implemented if they have been previously requested in writing and authorised.

4.1.2. Trials are also subject to this procedure.

4.1.3. Deviations are not subject to this procedure, but to operating instructions [enter doc. no. /version no.] “Handling deviations”.

4.1.4. Changes can be requested by any staff member using the change request form provided.

4.1.5. Changes of which the grade is debatable or unclear must also be requested using this procedure.

4.2. Implementation of change control procedures

4.2.1. Forms for change control procedures are issued by the QA department. If a new form is issued, a change number is automatically allocated to the change procedure by the change database and is entered on the form.

4.2.2. The applicant should specify the object of the change and the significant reasons and circumstances of the change on the change request. He/she should then sign and date it.

4.2.3. The heads of areas affected by the change should have the opportunity to give their opinion on the intended change, to identify any risks and to suggest necessary measures and schedules. In any case, they should be acquainted with the planned change. This is documented in no. 2 on the change request.

4.2.4. The QA representative transfers the data required to identify the procedure into the change control database.

4.2.5. The members of the CCC jointly carry out a risk analysis of the change request under no. 3.1, classify the change under no. 3.2 and give their decision to authorise or reject the change application. Under no. 3.3. Authorisation may be associated with a time scale. The applicants and their head of area are informed of the decision via a copy of the completed change request.

4.2.6. A decision by the CCC in accordance with 4.2.5 may only be made if all the information and documents relevant to the decision are submitted. If necessary, the request may be returned to the applicants for completion.

4.2.7. If the change is authorised, the CCC can establish a measure plan in the change request (tasks, responsibilities, schedule). This must be completed and authorised for the change procedure to be completed.

4.2.8. Those responsible in accordance with the measures plan shall each receive a copy of section 3.4 and shall inform the QA representative when the established measures have been completed.

4.2.9. The QA representative shall collect all the completed plans, check them for successful completion of each task and include them with the original change request. The completed change request is archived, and the result and date of the completion is entered in the change database.

4.2.10. In simple cases, in which the applicants can implement the changes themselves without requiring any scheduling, an electronic copy of the request may be distributed to the CCC via the internal e-mail system instead of at a meeting (circulation procedure). Each CCC member then gives a written vote regarding the change request via e-mail with electronic signature. The change request and electronic voting from the CCC members are archived.

4.3. If there is no unanimous decision, the QA representative calls a meeting to discuss the request.

4.4. Documentation

4.4.1. The procedure in accordance with chapter 4.2 must be documented on the "change request" form.

4.4.2. If necessary, documents relevant to the decision are added to the change request.

4.4.3. The change request and relevant documents concerning the decision must be kept indefinitely in the "quality assurance" area of the department.

4.4.4. If necessary, for capacity reasons, the paper copy of the change request and its associated documents may be replaced with an electronic archive file.

4.5. Deviation from the procedure

4.5.1. It is permissible to deviate from the regulations in chapter 4.2 only if:

- an immediate change is urgently required for operational or staff safety.
- an immediate change has considerable significance for the unit.
- the need for it was not foreseeable and it was not possible to comply with the formal procedure in chapter 4.2 in the time available.

4.5.2. In the event of chapter 4.4.1, the consent of the responsible head of area or his representative should be sought before the change is implemented.

4.5.3. Once the change has been implemented, the procedure in chapter 4.2 must be followed at the earliest opportunity.

Reference documents:

16.343. Annex 1: Form - Internal Audit Report

16.343. Annex 2: Form - Sample of Audit Checklist

16.343. Annex 3: Form - Internal Audit Report

16.343. Annex 4: Form - Internal Audit Monitoring

16.343. Annex 5: Flow chart - Internal Audit Programme

Special note for SMEs: A CCC might not always be possible due to lack of designated departments. In such cases, the owner/CEO/Managing Director has to decide how the SME handles the change control. They should stick to their company's most practical procedure.

15.0. SOP 338 (b) - Change control request form

Logo	**Standard format for SOP:** Change control procedures Department: _____ Policy No: _____

Change request form

Document number:	Version number:	Page of
File name:	Valid from:	Valid to:
Company:		
Change request: [cross reference to the operating instruction on which it is based].		
Change no.: (to be entered by QA)	Change designation: (to be entered by QA)	

1. Applicant Name:

1.1. Object of change (mark the appropriate box with a cross ☒

Manufacturing procedure	☐
Test procedure	☐
Cleaning procedure	☐
Other procedure	☐
Starting materials	☐
Packaging material	☐
Semi-manufactured/bulk product	☐
Finished medicinal product	☐
Other material	☐
Rooms	☐
Manufacturing facilities	☐
Quality control facilities	☐
Media supply	☐
Computer-assisted system	☐
Organisation	☐
Name/s of person/s who awarded/received the contract	☐
Supplier	☐
Marketing authorisation	☐
Documentation	☐

1.2. Description of change:

Cause/ reason for the change:

Products/ procedures/ facilities/ affected:
Necessary time frames:
Suggestion for implementing the change:
Estimated alternatives:
References: *[Cross reference to appendices where necessary]*
Date and signature of the applicant: .....

Scope

Alterations apply to all areas, sales, contract manufacturing and external testing places, as well as to printed packaging material.

Definitions and abbreviations

Change: planned deviation (extension, replacement, removal, addition) as part of a requirement.

Change control: a system with which qualified representatives from corresponding departments evaluate current or planned.

2. Area head	
[Response/risk assessment of the affected areas] Area:	
Date:	Signature: *of the person responsible]*

15.0. SOP 338 (c) - Change control approval form

Logo	**Standard format for SOP:** Change control procedures Department: _____ Policy No: _____

Change control approval

Document number:	Version number:	Page of
File name:	Valid from:	Valid to:
Company:		

3. Change control committee:

3.1. Additional risk assessments:

3.2. Grade of change: (mark the appropriate box with a cross ☒)

Major change	☐
Minor change	☐
No major or minor change	☐

3.3. Decision:

Has the change been authorised? Yes ☐ No ☐

Time limit for implementation:

If not authorised provide Rationale:

- If the change is authorised a time limit for the implementation must be stipulated.
- The measures list in no. 3.4 must be observed.
- If the change is not authorised. Provide a rationale.

Date and signature of the CCC members:

Head of Production:	Date:
Head of Quality Control:	Date:
Sales Manager:	Date:
Information Representative:	Date:
Head of Regulatory Affairs:	Date:
QA Representative:	Date:
Other members:	Date:

3.4. Measure's list

	[Directions for implementing and documenting the measure. *Cross references to affected documents that require revision. Extensive directions or project planning may be recorded in separate documents.]*
	Responsible:
	Time limit:
	Completed on:
	Signature:

4. QA head

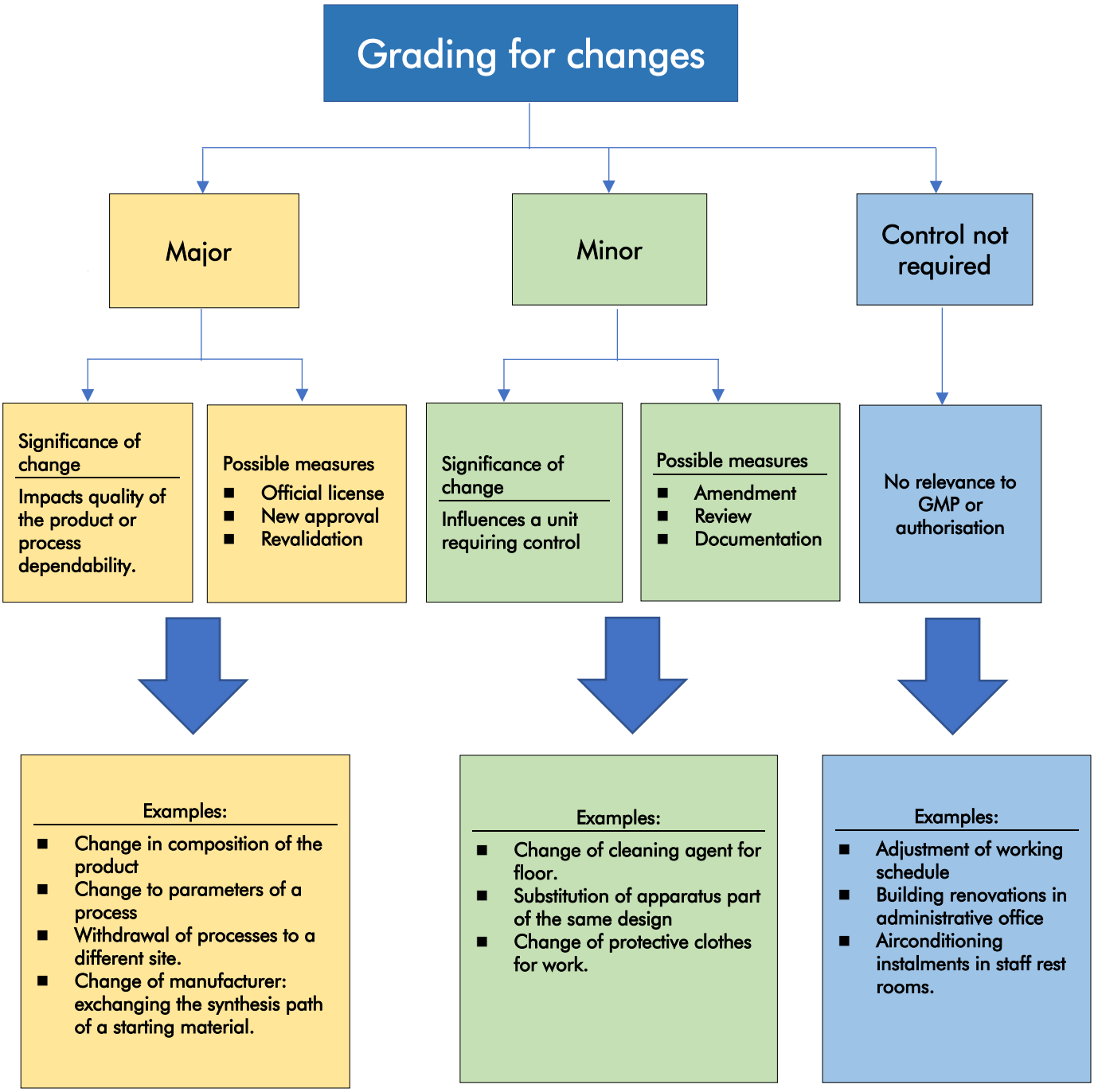
[Completion of procedure; (mark the appropriate box with an x)]

The procedure has been completed correctly:	Yes ☐	No ☐
It should be abandoned and not continued.	Yes ☐	No ☐

Rationale: Deviations occurred, and measures required for procedure completion

Signature of the QA head..... Date: _____

15.338. Annex 1- Flowchart: Change control grading system



16

NANCi Cosmetics Good Manufacturing Practices Manual and SOPs

Title: GMP Chapter 16: Internal Audit

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Chapter 16. Internal Audit

Introduction

An "Internal Audit" is defined as an independent inspection of a quality system. It evaluates the efficacy of the cosmetic company's management system. Internal auditing must be conducted by qualified individuals who operate independently, and the assessment must be carried out at regular intervals. Internal auditing will allow the manufacturer to identify the inadequacies in GMP implementation. The Internal Auditor will therefore provide the company with valuable recommendations for corrective and preventive actions. The process of internal auditing must include all written quality documents, instructions and records and cover all sections of GMP requirements to provide a clear gauge of the manufacturer's compliance to the GMP requirements pertaining to quality control and production.

Principle

The cosmetic manufacturer should ensure that the internal audit approach is independent and based on evidence. The auditor must be ethical, professional and fair of conduct. All undertakings pertaining to internal audits must be monitored by an independent party and comprise of a sampling plan and a tracking system which is clear, efficient and effective.

Internal auditors may be internal or external but work for the company.

Purpose

The purpose of this chapter is to explain the processes required, or resulting from internal audits. In addition, this chapter aims to define the responsibilities and advantages of internal audits within a quality management system. This chapter assists the manufacturer with planning, conducting and regulation of internal audits.

Scope

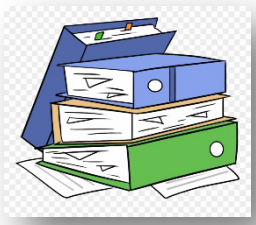
This chapter entails two stages of internal audit, the procedure and the follow-up. Internal audits will confirm that the product has been manufactured in compliance with GMP requirements and has been evaluated, monitored and approved accordingly. Furthermore, internal audits confirm the quality of application of GMP standards and its strategies. Internal audits will cover the evaluation of many aspects in the cosmetic company such as the performance of employees and key personnel, handling of customers, handling of consumers, dealing with government authorities and other institutions. This includes all documents, procedures and records comprising all components of GMP including the results of corrective and preventive actions.

Approach

Internal audits must be performed by qualified and assigned personnel. The internal auditors must be an independent party and must conduct periodical internal audits or audits on demand. All internal auditing documentation and evaluation results must be reported to management.

Follow-up

After evaluation by the auditing company/person, the company receives feedback from the auditee. The manufacturer/company must ensure that the feedback is satisfactory, and that Corrective Action and Preventive Actions (CAPA) are in place to evaluate the initial cause of any irregularity which may have been detected. The company is required to have a CAPA plan which is efficient, complete and properly documented. The final results from the investigation should be deemed satisfactory and documented. Additionally, CAPA must be conducted within the defined timeframe. The CAPA shall be verified and tracked by arranging a follow-up audit or requesting for an updated SOP.



Chapter 16 Internal Audit Checklist

Chapter 16 Internal audit checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	16.	**Internal Audit**					
	16.1	**Principle**					
	16.2	**Approach**					
328	16.2.1	Are internal audits conducted by trained personnel in an independent and detailed manner, regularly or on demand?					
*329	16.2.2	Are all observations made during the internal audit evaluated and shared with management?					
	16.3	**Follow-Up**					
330	16.3	Are corrective measures completed or implemented in a satisfactory manner , based on the observations?					

Reference:

IKW Cosmetics GMP based on ISO 22716

Website References:

A WHO guide to good manufacturing practice (GMP) requirements:https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1

ASEAN Cosmetic GMP Team: https://aseancosmetics.org/asean-cosmetics-directive/gmp-modules/

Pharma Change Control:https://www.fdanews.com/ext/resources/files/The_Food_And_Drug_Letter/2013/Pharma-Change-Control-Peither-ExecSeries.pdf

Pharmacautical guidelines:https://www.pharmaguideline.com/2014/08/sop-for-self-inspection-and-internal-audits.html

16.343. Annex 1: Form - Internal audit report

Good manufacturing practice (GMP) audit report	
Report Number:	Reference Number: [document number]
No.	
GMP reference	
Internal Audit findings	
Grading	
Location	
Auditee	
Auditor	

16.343. Annex 2: Form - Sample of audit checklist

Good manufacturing (GMP) internal audit checklist for assesment				
Date:		Location: [warehouse]		
Auditor:		Auditee:		
Description	**GMP reference**	**Parameter**	**Findings**	**Conforms [yes/no]**
Personnel	1.2.1	Organisational		
	5.1.2	Personnel hygiene		
	2.1.5	Training record		
Storage area	3.1.5	Design and layout of defined area		
	3.7.3	Flow of personnel and goods		
	4.1.5	Structure of the storage area, based on GMP		
	4.1.7	Record of monitoring parameter		
Sanitation	5.1.5	Pest program record		
	6.1.7	Weighing apparatus cleanliness		
Documentation	8.3.1	Records for maintenance and calibration of weighing apparatus		
	8.4.5	The effectiveness of the labelling system		
	9.1.1	Inventory stock control		
Change control	10.5.1	Flow chart		
	10.6.8	Responsibilities of staff		

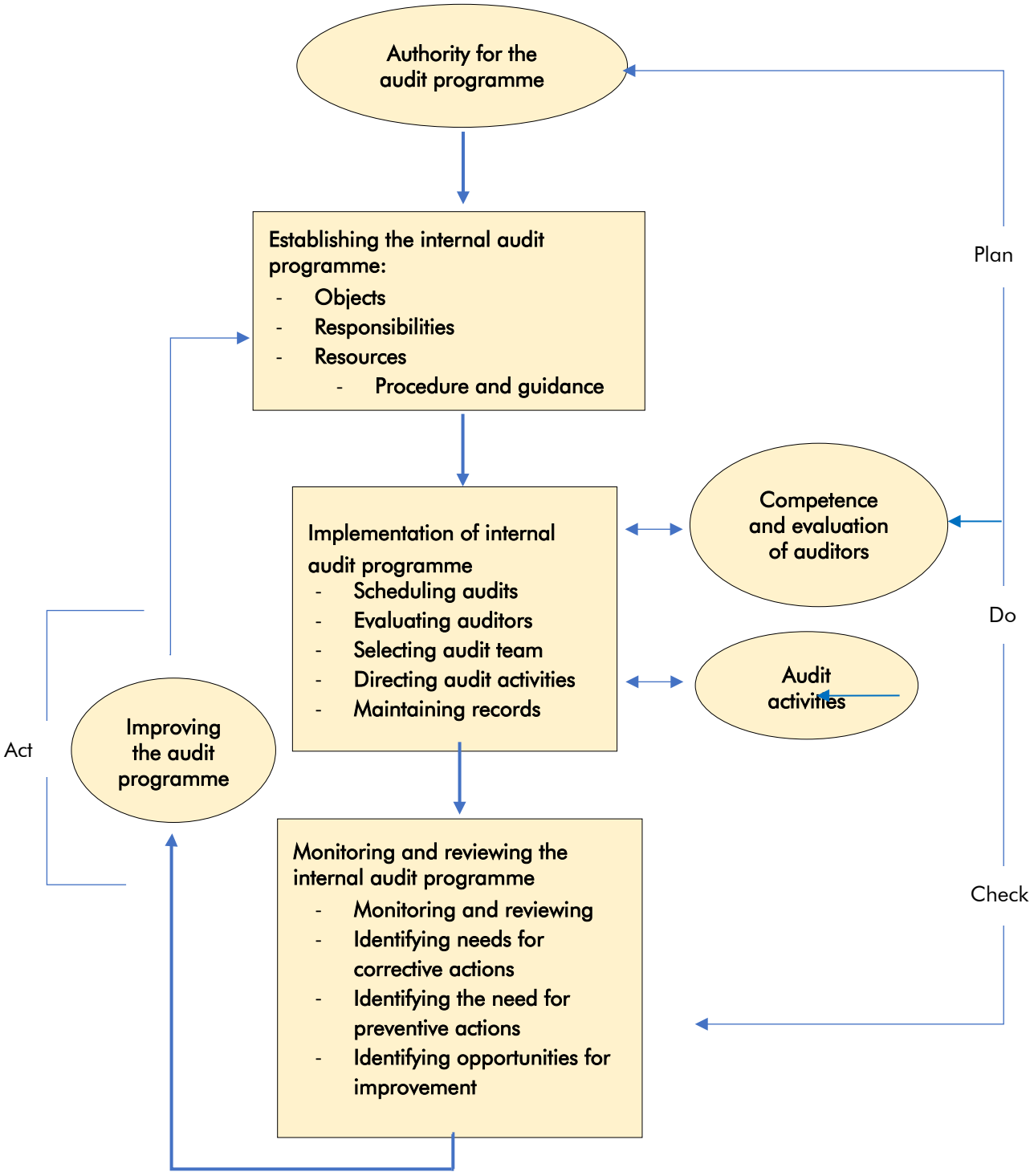
16.343. Annex 3: Form - Internal audit report

Audit report	
Title:	
Objectives	
Scope	
Audit plan	
Audit observations	
Classification	
Non-compliance	**Compliance**
a. Critical deficiency b. Major deficiency c. Minor deficiency	a. Satisfactory b. Outstanding
Recommendations/Expectations:	
Audit team leader:	Audit members:
Date:	Location: (site where activities were conducted)
Criteria:	Findings:

16.343. Annex 4: Form - Internal audit monitoring

Internal Audit: Questionnaire	
Area audited: _____	Date: _____
Question (in reference to GMP)	Response
1. Does the company have a work instruction to operate the machinery?	
2. How is the machine being cleaned and maintained?	
3. Are personnel trained to use the machine?	
4. How often is the equipment calibrated and cleaned?	
5. When was the last breakdown of the machine?	
6. Were any products affected?	

16.343. Annex 5: Flowchart - Internal audit programme



16.2. SOP 343 - Internal Audit and self inspection

Logo	**Standard format for SOP:** Internal audit and self inspection Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of: _____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to introduce the procedure for conducting internal audits and self inspection in selected departments in the cosmetic production. For general assessment of quality systems and procedures. To ensure compliance with applicable GMP requirements. To enhance the system and to perform corrective measure, where applicable.

Scope:

This SOP is applicable to the internal quality audit conducted in the different departments.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

QA Executive/QA officer

Accountability:

QA Head/QA Manager

Procedure:

1. Audit Scheme:
   - 1.1. To start the audit, complete the audit scheme form. Once completed, the form is passed to the Auditors, Auditee and Quality- or Factory Head.
   - 1.2. The audit scheme form shall contain the Audit Objective and Audit Scope as listed in this SOP.
2. Audit Objective:
   - 2.1. Explain the objective of the audit your are applying for. The objectives may be as follows:
     - To determine the conformity or non-conformity of the quality system elements with the specified requirements.
     - To determine the effectiveness of the implemented quality system in meeting the specified quality

objectives.

- To fulfill regulatory requirements.
- To assess the company's own system in contrast to cGMP (current Good Manufacturing Practices)

3. Audit Scope:
   3.1. The audit scope is structured specifically to fit the audit objective.
   3.2. Any documents required to conduct the audit are specified.
   3.3. Listed below are possible inputs for the scope of the audit:
   - Quality system elements
   - Organizational activities
   - Standard Operating Procedures (SOP).
   - Good Manufacturing Practices (GMP) or Good Laboratory Practices.
   - Documentation

4. Auditee:
   4.1. The Audit Scheme Form (ASF) includes the name of the department and the section to be audited.
5. Audit Team (Auditors):
   5.1. The ASF includes the name and department of the auditors who are to carry out the audit.
   5.2. The audits are conducted but not limited to a member of the QA department.
   5.3. A checklist is prepared by the audit team and the auditors for the audit.
   5.4. It is the responsibility of the auditors and audit team to prepare all required documents and to align the audit plan with the other members of the audit team.
6. Audit Schedule:
   6.1. The audit scheme form includes the date, duration and location of the audit.
7. Executing the Audit:
   7.1. Upon initiation of the audit, the auditor takes into account the following:
   - Any major non-conformities shall be reported to the auditee by the auditor immediately.
   - Auditors shall exercise impartiality.

8. Collecting Evidence:
   8.1. Evidence shall be accumulated through interviews, analysis of documents and examination of activities and circumstances in the region of concern.
   8.2. Randomly sample documents, activities and other related records to verify compliance.
9. Audit observations:
   9.1. All examinations are documented accordingly.
   9.2. Once all the activities have been audited, the assessments is reviewed by the audit team to identify any non-conformities which may have been reported.
   9.3. Non-conformities shall be defined in terms of certain requirements of the standard or associated documents.
10. Audit Report:

The Audit report contains but is not limited to the following items, as applicable.

- The objective and scope of the audit.
- Details of the audit team members, auditee's representative and audit dates.
- Documents audited.
- Observations of non-conformity mentioning the details of product name batch no., reference document no., page no., line no., date and the name of the person, whichever is applicable.
- The audit report distribution list.
- Based on the observations the auditor shall prepare a report.
- The audit report along with the observation shall be given to the Department Head concerned for response. A copy of the audit report shall be given to the Quality Head and Plant Head within 15 days after the audit.
- The QA department may issue a Corrective Action Request for the pending observation.
- Agree with the auditee on non-conformance and issue a copy of non-conformances to the auditee. The auditee will determine the causes of the non-conformances and indicate a plan to complete corrective action.

11. Corrective Action:
    - The auditee is responsible for determining and initiating corrective action needed to correct the cause of non-conformity.
    - The auditee shall respond in writing to each observation, which includes corrective action taken within 15 days after receipt of the audit report.
    - A Corrective Action Request may be given. The target date for closing of the Corrective Action Request shall be given in consultation with the auditee.
    - A follow up audit shall be done to confirm completion of pending corrective actions or to check the effectiveness of completed corrective action at the discretion of QA head.
    - After all the recommendations are implemented, the QA department closes the audit report.
12. Frequency: At least twice per year.

Definitions:

SOP: Standard Operating Procedure

QA: Quality Assurance

GMP: current Good Manufacturing Practices

Reference documents:

16.343. Annex 1: Form - Internal Audit Report

16.343. Annex 2: Form - Sample of Audit Checklist

16.343. Annex 3: Form - Internal Audit Report

16.343. Annex 4: Form - Internal Audit Monitoring

16.343. Annex 5: Flow chart - Internal Audit Programme

Annexure A: GMP in the Cosmetic Industry Questionnaire based on ISO 22716

Special note for For SME's:

Designated departments like the QA department might not exist, therefore, it is usually the owner/CEO/Managing Director that will carry out the internal audit. Since they are also the head of the company, special attention should be paid to exercising impartiality and objectivity.

Annexure A: GMP in the cosmetic industry questionnaire based on ISO 22716

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
	3	Personnel					
	3.1	Brief description					
	3.2	Organisation					
	3.2.1	Organisation chart					
1	3.2.1.1	Is there a current organisation chart, which is understandable, and which reflects the size of the plant and the range of products?					
2	3.2.1.2 (1)	Does exist for every staff member (respectively group of persons with the same job) a current job description and its classification in the organisational structure?					
3	3.2.1.2 (2)	Does exist for every staff member (respectively group of persons with the same job) information on qualification requirements, function, and responsibilities?					
4	3.2.1.3	Does the organisational chart reflect the independence of the quality unit (quality assurance / quality control) from other departments in the plant?					
	3.2.2	Is sufficiently trained personnel in place for all required activities mentioned in this guideline					
5	3.2.2 (1)	▪ in the manufacturing area?					
6	3.2.2 (2)	▪ in quality assurance and quality control?					
7	3.2.2 (3)	▪ in purchase department?					
8	3.2.2 (4)	▪ in material receiving-, storing- and shipping areas?					
	3.3	Main responsibilities					
	3.3.1	Responsibilities of the management					
9	3.3.1.1	Does the management support the organisation?					
10	3.3.1.2 (1)	Does the management accept the main responsibility for GMP?					
11	3.3.1.2 (2)	Does the management involve the personnel of all departments and positions in the implementation of GMP?					
12	3.3.1.2 (3)	Does the head of manufacturing have a scientific or technical education?					
13	3.3.1.2 (4)	Does the head of QA /QC have a scientific or technical education?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
14	3.3.1.3	Are there defined manufacturing areas, which can only be entered by authorised personnel?					
	3.3.2	Tasks of the staff					
15	3.3.2 a)	Does the staff know their position within the organisational structure?					
16	3.3.2 b)	Does the staff know their own defined areas of responsibility, tasks and activities?					
17	3.3.2 c) (1)	Does the staff have access to the documents that are valid for the respective area of responsibility / work area?					
18	3.3.2 c) (2)	Are the provisions of the documents in the respective areas of responsibility / work areas observed?					
19	3.3.2 d)	Does the staff comply with the regulations on personal hygiene?					
20	3.3.2 e)	Are irregularities or inconsistencies in the area of responsibility and work reported by the staff?					
21	3.3.2 f) (1)	Are the personnel sufficiently trained and competent to carry out the assigned tasks and activities? (see also 3.4)					
22	3.3.2 f) (2)	When using external personnel (temporary staff): Is it ensured that the personnel are sufficiently qualified and instructed to carry out assigned tasks properly (see requirements according to 3.4)?					
	3.4	Training / Instruction					
	3.4.1	Training and skills					
	3.4.2	Training and good manufacturing practice					
23	3.4.2.1	Is appropriate training on good manufacturing practice offered to all employees?					
24	3.4.2.2 (1)	Is the training need for all staff identified?					
25	3.4.2.2 (2)	Is a training programme developed and implemented based on the identified training needs?					
26	3.4.2.2 (3)	Is the training programme documented?					
27	3.4.2.3	Are the training measures adapted to the tasks and responsibilities, the expertise and experience of the individual persons?					
28	3.4.2.4	Are training courses / instructions developed and implemented by internal or external personnel?					
29	3.4.2.5 (1)	Are trainings / instructions regularly carried out and adapted to current conditions?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
30	3.4.2.5 (2)	Are training courses / instructions documented?					
31	3.4.2.5 (3)	Is it ensured that the staff attend or repeat the training courses intended for them?					
32	3.4.3	Are basic theoretical and practical training in good manufacturing practice and specific training in their tasks given to newly recruited employees?					
33	3.4.4	Is the knowledge acquired by staff identified and evaluated during or after training?					
	3.5	Hygiene measures and health status of staff					
	3.5.1	Hygiene					
34	3.5.1.1 (1)	Has a hygiene programme been drawn up for the production, quality control and storage areas?					
35	3.5.1.1 (2)	Is the hygiene programme adapted to the needs of the plant?					
36	3.5.1.1 (3)	Are the requirements set out in the hygiene programme understood and followed?					
37	3.5.1.2 (1)	Are facilities for hand washing and hand disinfection sufficiently available and equipped?					
38	3.5.1.2 (2)	Is the staff instructed in washing and disinfecting hands?					
39	3.5.1.2 (3)	Are the facilities for washing and disinfecting hands used regularly?					
40	3.5.1.3 (1)	Do manufacturing personnel wear appropriate and prescribed protective clothing to prevent contamination of cosmetic products?					
41	3.5.1.3 (2)	Do the quality control personnel wear appropriate and prescribed protective clothing to prevent contamination of cosmetic products?					
42	3.5.1.3 (3)	Do the storage personnel wear suitable and prescribed protective clothing to prevent contamination of the cosmetic products?					
43	3.5.1.4 (1)	Is there a ban on food and drink, chewing gum and smoking in the production, quality control and storage areas?					
44	3.5.1.4 (2)	Is there a prohibition in the production, quality control and storage area for storing food, drinks, smoking utensils, personal medicines?					
45	3.5.1.4 (3)	Is there a regulation in the manufacturing, quality control and storage area for the wearing of watches					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		and all kinds of jewellery (including wedding rings), artificial fingernails and visible piercings etc.?					
46	3.5.1.5	Is there an instruction for the manufacturing, quality control and storage areas that any unhygienic behaviour is prohibited in order to avoid product deterioration?					
	3.5.2	Health					
47	3.5.2	Are precautions taken to ensure that employees with illnesses and/or visible injuries are not deployed in the area of open products?					
	3.6	Visitors and untrained staff					
48	3.6 (1)	Are visitors and untrained personnel kept away from the manufacturing, quality control and storage areas?					
49	3.6 (2)	If it is not possible to keep away from the specified operating areas, is this group of persons instructed and supervised with regard to hygiene and prescribed protective clothing?					
50	3.6 (3)	Is there a regulation for the behaviour of visitors, untrained personnel and external craftsmen in the production, quality control and storage areas?					
	4	**Company grounds / manufacturing plant**					
	4.1	Brief description					
51	4.1.1 a)	Is the company site designed and used in such a way that the protection of materials and products is ensured?					
52	4.1.1 b)	Are effective cleaning, disinfection and maintenance of the premises possible?					
53	4.1.1 c)	Are the premises designed and used in such a way that the risk of confusion is minimized when products, raw materials and packaging materials are moved?					
54	4.1.2	Are areas of different hygienic requirements defined and marked and are the different hygienic areas basically assigned to sufficient hygienic measures?					
	4.2	Operating areas					
55	4.2	Are the storage, production, quality control, social rooms, sanitary rooms and other ancillary rooms separated from each other?					
	4.3	Premises					
56	4.3	Is there a sufficient number of rooms available?					
	4.4	Material and personnel flow					
57	4.4	Has the personnel and material flow been					

		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
		defined and is it being adhered to?					
	4.5	Floors, walls, ceilings, windows					
58	4.5.1 (1)	Are floors / walls / ceilings / windows in a good and clean condition?					
59	4.5.1 (2)	Are floors / walls / ceilings / windows designed to allow thorough cleaning?					
60	4.5.1 (3)	Are floors / walls / ceilings / windows designed in such a way that disinfection is possible?					
61	4.5.2	Are windows that can be opened into outdoor areas (e.g. into the open air or other production/storage rooms) designed in such a way that a negative influence on cosmetic products is not possible (e.g. fly screens)?					
62	4.5.3 (1)	Has the design of the manufacturing plant, depending on the type of product, been / is the suitable, crack-free and smooth floor condition taken into account?					
63	4.5.3 (2)	Has the optimal cleaning and disinfection been / is taken into account in the design of the manufacturing plant, depending on the type of product?					
64	4.5.3 (3)	Has the design of the manufacturing plant, depending on the type of product, taken into account the resistance of floors and walls to corrosive detergents and disinfectants?					
	4.6	Wash and WC area					
65	4.6	Are there sufficient toilets and washing facilities exclusively for the employees of the hygiene-relevant areas and can they be reached directly from the corresponding areas?					
	4.7	Lighting					
66	4.7	Is the lighting sufficient?					
67	4.7.2	Are the lamps secured against possible breakage?					
	4.8	Ventilation					
68	4.8	Is the ventilation sufficient and is it ensured that there is no negative influence on the cosmetic products (e.g. fly screens, ventilation with filter stages, no direct air flow onto the products)?					
	4.9	Pipelines, sewers and drains					
69	4.9.1 (1)	Are lines designed in such a way that in case of leakage no contamination of equipment, materials, cosmetic products etc. can be caused?					
70	4.9.1 (2)	Are lines designed in such a way that condensates cannot cause contamination					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		of equipment, materials, cosmetic products, etc.?					
71	4.9.1 (3)	Are lines designed in such a way that falling dirt cannot cause contamination of equipment, materials, cosmetic products etc.?					
72	4.9.2 (1)	Are sewage pipes designed so that they are always clean?					
73	4.9.2 (2)	Are sewage pipes and sluices designed in such a way that a backflow of sewage can be excluded?					
74	4.9.3 a)	Are exposed overhead beams, pipes, ducts, etc. avoided?					
75	4.9.3 b)	Are exposed pipes installed at a sufficient distance from the wall / ceiling to ensure thorough cleaning?					
	4.10	Cleaning and disinfection					
76	4.10.1	Is the manufacturing plant, and especially the hygiene-relevant areas, in a clean condition?					
77	4.10.2	Is there sufficient cleaning / disinfection to protect the product?					
78	4.10.3 (1)	Are the cleaning agents used specified?					
79	4.10.3 (2)	Are the specified cleaning agents effective?					
80	4.10.3 (3)	Are the disinfectants used specified?					
81	4.10.3 (4)	Are the specified disinfectants effective?					
82	4.10.4 (1)	Are cleaning / disinfection measures carried out with suitable, effective and specified means, tailored to the respective needs of individual areas?					
83	4.10.4 (2)	Are cleaning / disinfection measures documented?					
	4.11	Maintenance					
84	4.11	Is there a corresponding maintenance plan for buildings, premises etc.? Are the measures documented?					
	4.12	Consumables					
85	4.12	Is it ensured that consumables (e.g. lubricants, cleaning cloths, auxiliaries) do not have a negative impact on the cosmetic products?					
	4.13	Pest control					
86	4.13.1	Is the production plant designed in such a way as to prevent the intrusion of insects, small rodents, pests and other vermin, etc.?					
87	4.13.2	Is a pest control program in place and documented accordingly?					
88	4.13.3	Are there preventive measures in the					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		outdoor area that prevent nesting or intrusion (trees, waste containers, etc. at a sufficient distance from the buildings)?					
	5	Equipment / devices and installations					
	5.1	Brief description					
	5.2	Equipment design / plant design					
89	5.2.1	Is product contamination prevented by the equipment/devices and installations?					
90	5.2.2 (1)	Are the containers of bulk and intermediate products closed?					
91	5.2.2 (2)	Are the products and intermediate products protected against moisture, dust and contamination?					
92	5.2.3 (1)	Are decanting hoses and accessories cleaned / disinfected and then dried?					
93	5.2.3 (2)	Are decanting hoses and accessories stored in a dry place protected against dust, splashes and other impurities?					
94	5.2.4	Are the materials of the equipment/devices and systems compatible with the product, detergents and disinfectants?					
	5.3	Installation					
95	5.3.1	Is there good draining of the equipment / devices and installations to facilitate cleaning and disinfection?					
96	5.3.2	Are the equipment/devices and plants arranged in such a way that no impairment of the product quality by materials, mobile equipment and personnel is to be expected?					
97	5.3.3	Are the systems and equipment easily accessible on all sides for maintenance, cleaning and disinfection work?					
98	5.3.4	Are the plants / main equipment sufficiently marked and easily identifiable?					
	5.4	Calibration					
99	5.4.1	Are the measuring instruments important for product quality regularly calibrated in laboratories and in production?					
100	5.4.2	Are the measuring instruments marked and sorted out if the calibration results are outside the permitted limits?					
101	5.4.3	If unacceptable calibration results are obtained, are there appropriate investigations to determine whether there is any impairment of the produced product, and are appropriate measures taken (CAPA = Corrective action, preventive action)?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
102	Calibration Law	Law Are scales and measuring instruments checked regularly?					
103	Calibration Law	Are scales and measuring instruments regularly adjusted?					
	5.5	Cleaning and disinfection					
104	5.5.1 (1)	Is there a suitable cleaning and, if necessary, disinfection program for all equipment / devices and systems?					
105	5.5.1 (2)	Are CIP / SIP procedures used for system cleaning (cleaning-in-place, sterilization-in-place)?					
106	5.5.2 (1)	Are effective detergents and disinfectants specified?					
107	5.5.2 (2)	Is the effectiveness of the specified cleaning and disinfecting agents confirmed?					
108	5.5.2 (3)	Is the expiry date of detergents and disinfectants taken into account?					
109	5.5.3 (1)	Is the equipment/plant cleaned and, if necessary, disinfected at suitable intervals during successive or continuous productions?					
110	5.5.3 (2)	Is the cleaning / disinfection carried out and documented for continuous productions?					
111	5.5.3 (3)	Is the equipment / plant cleaned / disinfected at suitable intervals in the case of discontinuous production of several batches of the same product?					
112	5.5.3 (4)	Is the cleaning / disinfection carried out documented for discontinuous productions?					
	5.6	Maintenance					
113	5.6.1	Is there a service and maintenance programme for the equipment / facilities?					
114	5.6.2	Is it ensured that the maintenance measures do not impair the product quality?					
115	5.6.3	Are damaged pieces of equipment / installations identified, marked, excluded from use and, if possible, discarded?					
	5.7	Consumables / operating materials					
116	5.7	Is it ensured that the consumables / operating supplies used do not impair the product quality?					
	5.8	Authorisations					
117	5.8	Are the equipment or manufacturing facilities and control systems used in production and monitoring / control only operated by authorised / licensed personnel?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
	5.9	Security systems / redundancies					
118	5.9	Are suitable alternative systems (back up) available to continue the processes in case of malfunction or failure of systems?					
	6	**Starting and packaging materials**					
	6.1	Brief description					
119	6.1 (1)	Are specifications defined for all starting and packaging materials?					
120	6.1 (2)	Do all delivered starting and packaging materials meet the specified acceptance criteria, which are relevant for the quality of the final product?					
121	6.1 (3)	Do the specifications for starting materials and packaging materials define all test points that are relevant for the quality of the final product?					
122	6.1 (4)	Do the test points contain limit values set out in the specifications for starting and packaging materials as acceptance criteria?					
	6.2	Procurement					
123	6.2.a) (1)	Is there a procedure for assessing and selecting suitable material suppliers / manufacturers?					
124	6.2.a) (2)	Is the procedure for assessing and selecting suitable material suppliers / manufacturers reliably applied?					
125	6.2 a) (3)	Are the results of the supplier selection and evaluation documented?					
126	6.2 b)	Are formal provisions laid down, such as the type of selection to be made, acceptance criteria, procedure to be followed in the event of damage or alteration and transport conditions?					
127	6.2 c)	Do the agreements between the company and suppliers contain statements on the establishment and maintenance of relationships such as support and auditing by the client?					
	6.3	Goods receipt					
128	6.3.1 (1)	Is there a process for checking whether the order, delivery note and delivered material match?					
129	6.3.1 (2)	Are additional checks carried out on the identity of the manufacturer, if necessary?					
130	6.3.2 (1)	Are the shipping containers checked by visual inspection for intactness and, if necessary, with regard to the transport data?					
131	6.3.2 (2)	Are all incoming goods subjected to a defined sampling procedure?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
132	6.3.2 (3)	Are the cleaning agents and disinfectants adequately tested at goods receipt?					
133	6.3.2 (4)	Are sampling devices required for all raw materials?					
134	6.3.2 (5)	Are the prescribed or given sampling devices for raw materials suitable to ensure reliable quality control results?					
	6.4	Identification and status					
135	6.4.1 (1)	Are the starting materials marked with labels that contain information about the supplier / manufacturer, identity and batch?					
136	6.4.1 (2)	Are the starting materials marked with labels that contain information on the container number, quantity, gross/tare weight?					
137	6.4.2	Are inputs with visible defects that impair product quality held back until the decision on use is made?					
138	6.4.3	Are the materials physically marked "free", "blocked" or "quarantined" or is this ensured by another system with the same level of security?					
	6.4.4	Contains the material identification:					
139	6.4.4 a) -	▪ the product name on the delivery note?					
140	6.4.4 b) -	▪ the product name of the supplier / manufacturer and recipient (if different)?					
141	6.4.4 c) -	▪ the date of receipt and, where appropriate, the expiry date?					
142	6.4.4 d) -	▪ the supplier's name and manufacturer's name (if different)?					
143	6.4.4 e)	▪ the batch number of the supplier / manufacturer and recipient (if different)?					
	6.5	Release					
144	6.5.1 (1)	Is it ensured that only approved materials are used in the manufacturing process?					
145	6.5.1 (2)	Are there physical or alternative release systems for source and packaging materials? (see also section 9)					
146	6.5.2	Is the release carried out by authorised quality personnel?					
	6.5.3	If releases are issued partly or entirely on the basis of supplier certificates, then:					
147	6.5.3 (1)	▪ the technical requirements of the supplier have been evaluated?					
148	6.5.3 (2)	▪ the experience and knowledge of the supplier has been evaluated?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
149	6.5.3 (3)	▪ audits have been carried out at the supplier?					
150	6.5.3 (4)	▪ test procedures have been agreed with the supplier?					
	6.6	Storage					
151	6.6.1 / 6.6.2	Are the storage conditions suitable for the materials?					
152	6.6.3	Are specific storage conditions maintained and monitored?					
153	6.6.4	Are the materials stored in closed containers and not directly on the ground (e.g. on pallets)?					
154	6.6.5	Are repackaged and returned materials marked with the same label data as in the storage area?					
155	6.6.6	Are blocked materials and/or materials in quality inspection stored in a separate and appropriately designated area or managed by an appropriate data system?					
156	6.6.7 (1)	Does the FIFO principle ("first-in-first-out") apply when using materials?					
157	6.6.7 (2)	Is there a definition of the storage period?					
158	6.6.8 (1)	Are regular inventories carried out?					
159	6.6.8 (2)	Are significant differences investigated after inventories and corrective measures taken if necessary?					
	6.7	Re-evaluation					
160	6.7	Is a suitable system in place for re-testing and re-evaluation after the end of the storage period (expiry date)?					
	6.8	Quality of the production water					
161	6.8 (1)	Is the required water quality (product water, cleaning water) sufficiently defined (chemical, physical, microbiological)?					
162	6.8 (2)	Is there an up-to-date diagram for the water system with all pipes and aggregates?					
163	6.8 (3)	Are the sampling points sensibly defined in the water system?					
164	6.8.1	Is the water treatment system capable of providing the specified amount of water of suitable quality?					
165	6.8.2 (1)	Is the water quality regularly monitored / checked? (chemical, physical, microbiological)					
166	6.8.2 (2)	Are monitoring / verification measures and all results documented?					
167	6.8.3	Can the water treatment system be disinfected?					
168	6.8.4	Is continuous circulation ensured in the					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		water treatment system (reduction of the risk of contamination)?					
169	6.8.5 (1)	Is it ensured that the materials used for water treatment do not influence the water quality?					
170	6.8.5 (2)	Is it ensured that the materials used for water treatment do not influence the product quality?					
	7	**Production**					
	7.1	Brief description					
	7.2	Operations of bulk production					
171	7.2 (1)	Is a documented process in place to determine the appropriate manufacturing method for the industrial process?					
		(this also includes filling and packaging, see 7.3)					
172	7.2 (2)	Is it ensured that the manufacturing method reliably results in a finished product that meets the specified acceptance criteria?					
173	7.2 (3)	Is it ensured that, in the event of changes in the production processes (e.g. if the facilities, the production site or the raw materials are changed) and in the upscaling phase, the production method reliably results in a finished product that meets the acceptance criteria?					
	7.2.1	Availability of relevant documents					
174	7.2.1.1 (1)	Is relevant documentation available at every stage of production?					
175	7.2.1.1 (2)	Is each phase of bulk production documented in the manufacturing protocol?					
	7.2.1.2	Are part of the specification documentation:					
176	7.2.1.2 a)	▪ the equipment / plant used?					
177	7.2.1.2 b)	▪ the formula?					
178	7.2.1.2 c)	▪ the list of all starting materials (including batch number and quantity)?					
179	7.2.1.2 d)	▪ detailed operations for each manufacturing phase (e.g. filling sequences, temperatures, speeds, mixing times, sampling, cleaning / disinfection, quantity transfer)?					
	7.2.2	Checks before the start of bulk production					
180	7.2.2 a)	Are all documents relevant to the bulk production process available?					
181	7.2.2 b)	Are all source and packaging materials available and approved?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
182	7.2.2 c) (1)	Is the equipment operational?					
183	7.2.2 c) (2)	Is the equipment cleaned and, if necessary, disinfected?					
		Are exhaust air systems suitable for work processes with dust formation:					
184	7.2.2 c) (3)	▪ available?					
185	7.2.2 c) (4)	▪ sufficiently dimensioned?					
186	7.2.2 c) (5)	▪ correctly positioned?					
187	7.2.2 c) (6)	▪ functional?					
188	7.2.2 d)	Is it checked that at the start of the process the manufacturing area is free of material and documents from previous operations ("line clearance")?					
	7.2.3	Assignment of a batch number					
189	7.2.3 (1)	Does every batch of an intermediate product (e.g. filling material) have a batch number?					
190	7.2.3 (2)	Can the batch number of an intermediate product be easily assigned to the batch number of the final product?					
	7.2.4	Marking of in-process operations					
191	7.2.4.1 (1)	Are all starting materials measured / weighed according to the recipe?					
192	7.2.4.1 (2)	Are all measured / weighed starting materials filled into suitable, appropriately labelled and clean containers or directly into the mixing container of the bulk production?					
193	7.2.4.2 (1)	Is it possible to identify the main equipment and the containers with the raw materials contained therein at any time?					
194	7.2.4.2 (2)	Is it possible to identify the main equipment and the containers with the intermediate products contained therein at any time?					
	7.2.4.3	Contains the labelling of the containers with the intermediate products:					
195	7.2.4.3 a) -	Designation or material number?					
196	7.2.4.3 b) -	Batch number?					
197	7.2.4.3 c) -	Storage conditions (if important for product quality)?					
	7.2.5	In-process control					
198	7.2.5.1 (1)	Are in-process controls defined with acceptance criteria?					
199	7.2.5.1 (2)	Are the in-process controls and their results documented?					
200	7.2.5.2	Are the in-process controls carried out according to a defined programme?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
201	7.2.5.3 (1)	Are in-process control results outside the acceptance criteria reported?					
202	7.2.5.3 (2)	Are investigations and follow-up measures initiated for in-process control results outside the acceptance criteria?					
	7.2.6	Storage of intermediate products / bulk					
203	7.2.6.1	Are the intermediate products stored in suitable containers, in defined areas and under suitable conditions?					
204	7.2.6.2	Is a maximum permitted storage time for intermediate products defined?					
205	7.2.6.3	Is there a fixed procedure when this storage time is exceeded?					
	7.2.7	Re-storage of starting materials					
206	7.2.7	Are residual amounts of starting materials stored in closed, labelled containers?					
	7.3	Filling, packaging and finishing operations					
	7.3.1	Availability of relevant documents					
207	7.3.1.1 (1)	Are there adequate instructions for carrying out each stage of the filling, packaging and wrapping process?					
208	7.3.1.1 (2)	Is every phase of filling, packaging and packing documented in the production protocol?					
	7.3.1.2	Are part of the specification documentation:					
209	7.3.1.2 a)	the equipment / plant used?					
210	7.3.1.2 b)	the list of packaging materials?					
211	7.3.1.2 c)	the listing of the individual packaging steps (filling, sealing, labelling, providing with identification numbers)?					
	7.3.2	Checks before the start of bottling, packaging and final packing					
212	7.3.2 a)	Is a check made before starting that the entire area is free of material from previous operations ("line clearance")?					
213	7.3.2 b)	Is it checked whether all relevant documents are available before the process starts?					
214	7.3.2 c)	Is it checked before the process starts whether all necessary packaging materials are available and approved?					
215	7.3.2 d) (1)	Is the equipment checked for functionality before the process starts?					
216	7.3.2 d) (2)	Is a check made before the process begins to ensure that the equipment has been cleaned and, if necessary, disinfected?					
		Are exhaust air systems suitable for work					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		processes with dust formation:					
217	7.3.2 d) (3)	available?					
218	7.3.2 d) (4)	sufficiently dimensioned?					
219	7.3.2 d) (5)	correctly positioned?					
220	7.3.2 d) (6)	functional?					
221	7.3.2 e)	Are reference numbers (markings / labels) available to enable the identification of materials and product?					
	7.3.3	Assignment of a batch number					
222	7.3.3.1	Does every batch of an end product have a batch number?					
223	7.3.3.2	Is there a traceable link between the intermediate product batch and the final product batch? (Traceability?) (see also 7.2.3)					
	7.3.4	Identification of the packaging line / packaging line					
224	7.3.4	Can the packaging line be identified from the end product and its batch number?					
	7.3.5	Checks of the equipment / devices and installations for online control					
225	7.3.5	With online control, is the equipment regularly checked according to a specified program?					
	7.3.6	In-process control					
226	7.3.6.1 (1)	Are in-process controls with acceptance criteria defined during packaging?					
227	7.3.6.1 (2)	Are the in-process controls and their results documented?					
228	7.3.6.2	Are in-process controls carried out according to a fixed programme?					
229	7.3.6.3	Are in-process control results outside the acceptance criteria reported? Are investigations and follow-up measures initiated?					
	7.3.7	Re-storage of packaging materials					
230	7.3.7	Are residual quantities of packaging materials stored in closed, labelled containers or outer packaging?					
	7.3.8	Identification and handling of unfinished products					
231	7.3.8	Is confusion or incorrect labelling impossible if the filling and labelling processes are carried out at different times?					
	8	**End products / finished products**					
	8.1	Brief description					
	8.2	Release					
232	Calibration	Are there binding specifications including					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
	Law / ISO 2859-1	acceptance criteria?					
233	8.2.1 (1)	Are end products / finished products tested according to specified test procedures before being placed on the market?					
234	8.2.1 (2)	Is it ensured that end products / finished products meet the acceptance criteria before being placed on the market?					
235	8.2.2 (1)	Does the product release take place through the personnel authorised for quality?					
236	8.2.2 (2)	Is product release adequately documented?					
	8.3	Storage					
237	8.3.1	Are the final products / finished products stored in defined areas under suitable (if necessary, monitored) conditions and for a reasonable period of time?					
238	8.3.2	Are the storage areas appropriately equipped and organised for this purpose?					
239	8.3.3	Are released, quarantined or blocked end products / finished products stored in their respective designated area or is a data system in place to ensure separation?					
	8.3.4	Are the containers with the end products / finished products (shipping unit and / or pallet) marked with:					
240	8.3.4 a)	▪ Description or code number (material number)?					
241	8.3.4 b)	▪ Batch number?					
242	8.3.4 c)	▪ Storage conditions (if necessary for product quality)?					
243	8.3.4 d)	▪ Quantity?					
244	8.3.5	Is the end product / finished product with the oldest release date used first (FIFO principle)?					
245	8.3.6 a)	Are inventories carried out at regular intervals?					
246	8.3.6 b) (1)	Are quantities recorded during the inventory according to quality status?					
247	8.3.6 b) (2)	Is any significant discrepancy investigated after the inventory?					
	8.4	Shipping					
248	8.4 (1)	Are there measures in place to ensure that the correct and approved end product / finished product is shipped?					
249	8.4 (2)	Are provisions made for the dispatch of the end products / finished products in					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		order to maintain product quality?					
	8.5	Returns					
250	8.5.1	Are returns marked and stored in specific areas?					
251	8.5.2	Is there a returns evaluation based on defined criteria?					
252	8.5.3	Are returns released again before being placed on the market again?					
253	8.5.4 (1)	Can post-processed returns be clearly identified?					
254	8.5.4 (2)	Is unintentional reintroduction into the market of not yet released, returned end products / finished products excluded?					
	9	**Quality Control Laboratory**					
	9.1	Brief description					
255	9.1.1	Do the principles described for personnel, premises, equipment, subcontracting and documentation also apply to the quality control laboratory?					
256	9.1.2	Is the quality control laboratory responsible for sampling, control and release within defined acceptance criteria?					
	9.2	Test procedure					
257	9.2.1 (1)	Does the quality control laboratory use test procedures necessary to establish the conformity of the product with the acceptance criteria at an appropriate frequency?					
258	9.2.1 (2)	Does the quality control laboratory use test procedures for the control of intermediate products and materials (starting and packaging materials) required to establish compliance with the acceptance criteria at an appropriate frequency?					
259	9.2.2 (1)	Are the checks carried out on the basis of established, appropriate and available testing procedures?					
260	9.2.2 (2)	Insofar as tests are dynamised: Is it ensured that the tests are carried out at a reliable frequency and are sufficient rules for dynamisation established?					
	9.3	Acceptance criteria					
261	9.3	Have acceptance criteria been established to define the requirements that starting materials, packaging materials, intermediate products and final products must fulfil?					
	9.4	Results					
262	9.4 (1)	Are all laboratory results documented?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
263	9.4 (2)	Are all laboratory results evaluated?					
264	9.4 (3)	Is this evaluation used to decide on a release or block or to temporarily suspend the decision (quarantine)?					
265	9.4 (4)	Is the usage decision derived from the inspection results adequately documented (separately from the results execution)?					
	9.5	Results not in accordance with specifications					
266	9.5.1	Are non-conforming results checked and investigated by authorised personnel and then a decision on their use made?					
267	9.5.2	Are repeat tests sufficiently justified and the decision documented?					
268	9.5.3	After the re-examination, is a decision regarding a deviation or refusal or the decision to suspend temporarily taken only by authorised personnel?					
	9.6	Reagents, solutions, standards, culture media					
		Reagents, solutions, standards and culture media are marked with:					
269	9.6 a)	▪ Name?					
270	9.6 b)	▪ Concentration or strength?					
271	9.6 c)	▪ Expiration date / expiry date, date of manufacture and batch identification?					
272	9.6 d)	▪ Name and / or signature of the person who made it?					
273	9.6 e)	▪ Opening date?					
274	9.6 f)	▪ Storage conditions?					
275	9.6 g)	▪ Labelling according to the Ordinance on Hazardous Substances?					
	9.7	Sampling					
276	9.7.1	Are the samples taken by authorised personnel?					
	9.7.2	The following aspects are specified for sampling:					
277	9.7.2 a)	▪ Sampling procedure?					
278	9.7.2 b)	▪ equipment to be used?					
279	9.7.2 c)	▪ quantity to be withdrawn?					
280	9.7.2 d)	▪ Precautions to protect against contamination/contamination or quality degradation?					
281	9.7.2 e)	▪ Identification of the sample?					
282	9.7.2 f)	▪ Frequency of sampling?					
	9.7.3	Contain the samples for clear traceability:					
283	9.7.3 a)	▪ Description or code number (material					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		number)?					
284	9.7.3 b)	▪ Batch numbers, own and supplier / production numbers?					
285	9.7.3 c)	▪ Date of sampling and time, if applicable?					
286	9.7.3 d)	▪ container from which the sample was taken?					
287	9.7.3 e)	▪ Sampling point, if applicable?					
	9.8	Sample storage / retained samples					
288	9.8.1	Are the end product samples / finished product samples stored in a suitable manner and in appropriate, defined areas?					
289	9.8.2	Does the size of the final product samples / finished product samples allow the performance of necessary analyses in accordance with local regulations?					
290	9.8.3	Are samples of finished products kept in their primary packaging for a reasonable period of time under the storage conditions recommended by the manufacturer? (Product liability according to 85/374/EEC Art. 7e must be observed)					
291	9.8.4 (1)	Are samples of the starting materials, especially raw material and possibly bulk batches, stored according to internal company regulations?					
292	9.8.4 (2)	Are samples of the starting materials stored in accordance with local regulations?					
	10	**Treatment of products not in accordance with specifications**					
	10.1	Rejected finished products, intermediate products, starting materials and packaging materials					
293	10.1.1	Is the examination of rejected finished / intermediate products or starting / packaging materials carried out by authorised personnel?					
294	10.1.2	Is the decision about rejected product / material (destruction, rework) taken by the personnel responsible for quality (assurance)?					
	10.2	Reworked finished products and intermediate products					
295	10.2.1	Is the decision to rework or to re-mix of not conforming (intermediate) products taken only by the personnel responsible for quality (assurance)?					
296	10.2.2	Is the procedure for re-processing or refurbishment defined and approved?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
297	10.2.3	Are the reworked end or intermediate products inspected by authorised personnel and the corresponding results evaluated to confirm conformity with the acceptance criteria?					
	11	**Waste**					
	11.1	Brief description					
298	11.1	Is waste disposed of promptly and hygienically?					
	11.2	Waste types					
299	11.2 (1)	Are the types of waste from the given production processes defined, which can influence the quality of the final products?					
300	11.2 (2)	Are the types of waste from the quality control laboratories defined, which can influence the quality of the final products?					
	11.3	FI / disposal routes					
301	11.3.1	Does the waste flow / disposal process in production and laboratories not affect the work processes?					
302	11.3.2 (1)	Are measures taken with regard to the collection, transport, storage and disposal of waste?					
303	11.3.2 (2)	Are the individual steps in the collection, transport, storage and disposal of waste documented in an appropriate manner?					
	11.4	Containers					
304	11.4	Are the waste containers adequately labelled (with additional information if necessary)?					
	11.5	Disposal					
305	11.5 (1)	Is waste disposal carried out in an appropriate manner?					
306	11.5 (2)	Is the waste disposal monitored?					
	12	**Subcontracting / service and contract manufacturing**					
	12.1	Brief description					
307	12.1 (1)	Is subcontracting / service or contract manufacturing defined by a written contract?					
308	12.1 (2)	Does the contract clearly define the requirements for the product or service by the contracting authority?					
	12.2	Types of subcontracting					
	12.2	Are the contracts and requirements for the following types of subcontracting clearly defined:					
309	12.2 a) (1)	▪ production of bulk intermediate?					
310	12.2 a) (2)	▪ production of bulk product?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
311	12.2 b) (1)	▪ filling bulk product in primary packaging?					
312	12.2 b) (2)	▪ packaging in primary packaging = consumer unit?					
313	12.2 b) (3)	▪ packaging in secondary packaging = trade unit?					
314	12.2 b) (4)	▪ packaging in tertiary packaging = pallet unit?					
315	12.2 c) (1)	▪ sensory analysis?					
316	12.2 c) (2)	▪ chemical analysis?					
317	12.2 c) (3)	▪ physical analysis?					
318	12.2 c) (4)	▪ microbiological analysis?					
319	12.2 d)	▪ cleaning and disinfection measures in the manufacturing plant?					
320	12.2 e)	▪ pest control?					
321	12.2 f) (1)	▪ maintenance and servicing of equipment and installations?					
322	12.2 f) (2)	▪ maintenance and repair of premises and buildings?					
	12.3	Client					
323	12.3.1 (1)	Does the client assess whether the contractor can carry out the tasks as agreed?					
324	12.3.1 (2)	Does the client assess whether the contractor is able to meet cosmetic GMP requirements (according to ISO 22716)?					
325	12.3.1 (3)	Is the decision for a contractor sufficiently documented?					
		Where the contracting authority ensures that the contractor has the means necessary to perform the contract:					
326	12.3.1 (4) -	▪ technical equipment / installations and devices?					
327	12.3.1 (5) -	▪ suitable buildings and premises (manufacturing plant)?					
328	12.3.1 (6) -	▪ suitable and sufficient personnel?					
329	12.3.2	Is all the information necessary for the proper execution of the tasks provided by the client (e.g. default documents such as specifications, manufacturing instructions, additional information, etc.)?					
	12.4	Contractor					
	12.4.1	Is ensured by the contractor that he is able to meet the contractually specified requirements:					
330	12.4.1 (1)	▪ has the necessary resources?					
331	12.4.1 (2)	▪ has the necessary experience?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
332	12.4.1 (3)	▪ has the necessary competent personnel?					
333	12.4.2 (1)	Is it ensured that the contractor does not pass on to third parties any tasks entrusted to him without the prior approval and consent of the client?					
334	12.4.2 (2)	Is it ensured by the contractor or third parties involved that all information on the tasks is available to the client as set out in the contract / agreement?					
335	12.4.2 (3)	Is the information to be provided to the contracting authority by the contractor or third parties involved defined?					
336	12.4.3 (1)	Are controls and audits by the client at the contractor contractually fixed?					
337	12.4.3 (2)	Does the contractor enable the contractually agreed controls and audits?					
338	12.4.4	Does the contractor inform the client of any planned changes that could affect the quality of the services or products (note: "change control")?					
	12.5	Contract					
339	12.5.1	Are the duties and responsibilities (delimitation of duties / responsibilities, "matrix") of both parties defined in the contract?					
340	12.5.2	Does the contractor keep all data available for the client or make them available to the client?					
	13	**Deviations**					
341	13.1 (1)	Are measures in place to regulate the procedure in case of deviations from specified requirements? (Authorisation, procedure) (see also section 15)					
342	13.1 (2)	Is there sufficient data to support the decision in case of deviations from established agreements?					
343	13.2	Are the corrective measures implemented in such a way as to avoid further deviations?					
	14	**Complaints and recall**					
	14.1	Brief description					
344	14.1.1	Are all complaints, that fall within the scope of this guide and are reported to the factory, reviewed, investigated and followed up if necessary?					
345	14.1.2 (1)	If a product recall is decided, are appropriate measures taken to carry out the recall in accordance with the GMP guidelines?					
346	14.1.2 (2)	Does the process for a recall clearly					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		define the responsibility and decision-making level up to management?					
347	14.1.2 (3)	If a product recall is decided, are appropriate corrective and preventive measures initiated?					
348	14.1.3	Is the process of handling complaints in the case of subcontracting of activities agreed between the client and the contractor? (see 12.1)					
	14.2	Complaints about products					
349	14.2.1	Are complaints centrally managed by authorised personnel?					
350	14.2.2	If a product defect is claimed, is the original information kept together with the follow-up information?					
351	14.2.3	Are appropriate follow-up measures (corrections) carried out for the affected batch of the product under complaint?					
	14.2.4	Include investigations to determine the cause of the fault and follow-up actions:					
352	14.2.4 a)	Steps to avoid repetition of errors (introduction of corrective measures)?					
353	14.2.4 b)	Checks of further batches to determine whether these are also affected?					
354	14.2.5	Are complaints checked at regular intervals in order to be able to detect trends or a repeated occurrence of the fault as a precautionary measure?					
	14.3	Recall of products					
355	14.3.1	Is the recall process coordinated by the authorised personnel?					
356	14.3.2	Are product recalls initiated in time and without delay?					
357	14.3.3	Are the competent authorities informed of recalls that could have an impact on consumer safety? (see Article 5 of Regulation (EC) 1223/2009)					
358	14.3.4 (1)	Are recalled products stored separately in a safe area until a decision on further action is taken?					
359	14.3.4 (2)	Are all activities in connection with the recall documented?					
360	14.3.5	Is the product recall process evaluated at regular intervals?					
	15	**Change control**					
361	15 (1)	Is a process defined for changes (equipment, material, process, etc.) that may affect product quality?					
362	15 (2)	Does the process ensure that all possible effects of the change (if necessary also on other processes / process parts) are					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
		considered?					
363	15 (3)	Are changes made only by specified, authorised personnel?					
364	15 (4)	Are changes always approved and implemented on the basis of sufficient data?					
365	15 (5)	Is it taken into account that changes may also have an impact on requirements derived from Regulation (EC) 1223/2009 (e.g. safety assessment, declaration of ingredients)?					
366	15 (6)	Is there documentation of the changes?					
	16	**Internal audit**					
	16.1	Brief description					
	16.2	Approach					
367	16.2.1	Are internal audits carried out independently and in detail by specially commissioned, competent personnel at regular intervals or as required?					
368	16.2.2	Are all observations of the internal audit documented, evaluated and communicated to management?					
	16.3	Follow-up investigation / tracking					
369	16.3	Are appropriate corrective actions based on the observations implemented and documented in a reliable and satisfactory manner?					
	17	**Documentation**					
	17.1	Brief description					
370	17.1.1/17.1.2	Has the company defined and implemented a suitable documentation system that is appropriate for the respective organisational structure and the type of products, and does it maintain this system?					
	17.2	17.2 types of documents					
371	17.2.1 / 17.2.2	Does the documentation system contain all procedures, specifications, inspection requirements, reports, procedures and records (in printed or electronic form) relating to the activities covered by the GMP Guide?					
	17.3	Written form, approval and distribution					
372	17.3.1	Do the specified documents describe the relevant operations, precautions and measures with the necessary detail?					
373	17.3.2	Will the title, nature and purpose of the documents be indicated?					
	17.3.3	Are the documents:					
374	17.3.3 a)	▪ legible and comprehensive?					

		Designation	Complied with				Note
			As a whole	Partly	Not	N/A	
375	17.3.3 b)	▪ approved, signed and dated before use by authorised personnel?					
376	17.3.3 c)	▪ prepared, updated, revoked (withdrawn), distributed and categorized (secret)?					
377	17.3.3 d)	▪ provided with a reference to ensure that no outdated documents are used?					
378	17.3.3 e)	▪ made available to the responsible personnel?					
379	17.3.3 f)	▪ removed from the workspace and destroyed when they are no longer current?					
	17.3.4	Contain records that require handwritten entries:					
380	17.3.4 a)	▪ details of what is to be entered?					
381	17.3.4 b)	▪ legible, document-proof entries?					
382	17.3.4 c)	▪ signature and date?					
383	17.3.4 d)	▪ corrections which leave the original registration legible and, where appropriate, the reason for the correction?					
	17.4	Revision					
384	17.4	Are documents revised if necessary and provided with revision reason and revision number or reason of issue and version number?					
	17.5	Archiving					
385	17.5.1	Are only original documents or verified copies archived?					
386	17.5.2	Does the archiving period comply with applicable legal provisions (product liability 85/374/EEC Art. 11) and internal regulations?					
387	17.5.3 / 17.5.4	Are stored documents (in paper or electronic form) readable and secure?					
388	17.5.5	Is backup data stored / saved separately at regular intervals in a safe place?					

NANCi Cosmetics
Good Manufacturing Practices
Manual and SOPs

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	Prepared by	Reviewed	Approved by
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	Date	By (Name and Position)	Signature
Implemented:			
Reviewed:			
Revised:			

Table of Contents

Chapter 17. Documentation

Introduction

The correct documentation will ensure that the GMP standard is complied with and may serve as reliable evidence thereof. Documentation is a fundamental part of quality assurance and pertains to all characteristics of the GMP standard. It is therefore recommended to provide training sessions to staff concerning the method of documentation, and the cosmetic manufacturer must ensure that a good documentation system is in place. A good documentation system will provide easy access to documents for auditors, as well as provide assurance that quality related activities are performed as planned and approved.

Principle

The cosmetic manufacturer ensures the establishment and implementation of a good documentation system that fits the cosmetic company's organisational structure and the types of products manufactured. The cosmetic manufacturer must ensure that this documentation system is properly maintained and controlled by the authorities entitled to do so .

Purpose

The aim of this chapter is to promote clear written and oral communication both for internal and external purposes. It is important that staff are well informed about their duties and responsibilities within the company. There should be proper documentation in place for specifications of all materials, manufacturing procedures and control. This should make it possible to easily conduct an audit trail especially in the event of presumed inadequate batches. The authorised personnel should have all information required to make the necessary decisions on batch release. The implementation of clear documentation will prevent errors, provide assurance that activities are conducted according to planned and approved procedures, ensure that responsibilities and authorities are identified by staff and will form the basis of the overall improvement of the product quality.

Scope

This chapter will cover important aspects on how to create a good documentation system, the manufacturing/distribution of documents, the types of documents needed to meet GMP requirements, how to conduct revision as well as the archiving of documents.

Types of documents

The key to operating a GMP-compliant company is proper documentation. The cosmetic manufacturer therefore ensures that a quality system for documentation is in place. All factors, requirements and supplies applied or used by the cosmetic company must be documented in a systematic, well organised, comprehensible manner which ensures that policies and procedures are followed. A documentation network can assist in categorising the different types of documents required for GMP compliance. Documents can be constructed in a variety of formats depending on the requirement, and can be either narrative, a flowchart, narrative and flowchart, or electronic system. In order to fulfil the GMP requirements of 22716 the cosmetic manufacturer must ensure that the following documents are established :

- Master formulation plan for each manufacturing process.

- Each stock-keeping unit should have a packaging instruction.
- Suitable labels for all the equipment, apparatus, containers and demarcated areas.
- Manufacturing procedures/processes should be accompanied by batch processing documents and records.
- SOP's for every manufacturing operation and facility operation except for product specific operations.
- Records and documents for everything related to batch packaging operations.

It is also helpful to compile stock control records and distribution records for warehouse materials. A water quality guidebook will be useful in providing clarity on water system designs, maintenance procedures, functionality and quality sampling of water.

Writing, Approval and Distribution

Distribution of documents must be meticulously planned in order to ensure that the most recent version is used. A distribution list should be developed and attached to the document. Unauthorised photocopying of original documents is forbidden. (Some companies manage this by having part of the front page printed in colour, or by using an official stamp or other means of identification). The cosmetic company must have written SOP's for the recovery, distribution and formulation of documentation. A list of all the documents is necessary to ensure that change control over all documents is well managed.

Revision

Documents should be reviewed regularly; however, the definition of "regular" will vary from company to company and in accordance with the document in question. Although not a GMP requirement, it is useful for all master copies to have a "review-by" date. Alternative methods of identifying the need for review include diaries or electronic reminders. The key is to have a system. After the review date has exceeded, and if no changes are necessary, the document will receive an endorsement to inform staff that the document has been reviewed and the "review-by" date is then amended. If amendments are necessary to the document, the history of changes is attached at the bottom of the document. Where changes are required, it is imperative that all obsolete or old copies are extracted and substituted with the newly amended documents. The procedure to rectify errors in a quality document is as follows:

- Draw a line-through an incorrect entry
- Insert the correct entry
- Mark or write down the explanation/reason for the change or correction
- Insert your initial /date of correction at the bottom of the document

Archiving

It is important to archive all original documents for a specified period of time or as legally required (usually 5 years for self-employed individuals). Documents may be archived electronically or in hard-copy format provided that legibility can be ensured. Any back-up data should be stored in a separate and secure location.

Checklist: Chapter 17 Documentation checklist

Chapter 17 Documentation checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
	17	**Documentation**					
	17.1	**Principle**					
331	17.1.1	Does the company have an adequate system for documentation and does this system adhere to the organisational structure and the types of products? Does the company maintain such a system?					
	17.2	**Types of documents**					
332*	17.2.1 / 17.2.2	Does the documentation system include all instructions, specifications, test protocols, reports, methods and records appropriate to the activities covered by the GMP guidelines? (as hard copy paper or electronic data processing record)					
	17.3	**Writing, Approval and Distribution**					
333*	17.3.1	Do the defined documents describe the corresponding operations to be carried out, precautions to be taken and measures to be applied with appropriate detail?					
334	17.3.2	Are the title, nature and purpose of documents stated?					
	17.3.3	**Are the documents:**					
335	17.3.3a	▪ legible?					
336	17.3.3b	▪ approved, signed and dated by authorised person/s before being used?					
337	17.3.3c	▪ prepared, updated, withdrawn, distributed and classified (confidential)?					
338	17.3.3d	▪ endorsed to ensure that obsolete documents are not used?					
339	17.3.3e	▪ made available to the relevant personnel?					
340	17.3.3f	▪ removed from the job area and destroyed if they are outdated?					
	17.3.4	**Do records which require the entry of handwritten data include:**					
341	17.3.4a	▪ indications as to what is to be entered?					
342	17.3.4b	▪ legible entries, with permanent ink?					
343	17.3.4c	▪ signature and date?					
344	17.3.4d	▪ corrections which leave the original entry legible and is the reason for the correction noted on the document?					
	17.4	**Revision**					

Chapter 17 Documentation checklist							
		Designation	Complied with				**Note**
			As a whole	Partly	Not	N/A	
345	17.4.1	Are documents, where necessary, updated and is the reason for revision and number and / or reason for the revision and version number stated?					
	17.5	**Archiving**					
346*	17.5.1	Are only original documents or controlled copies archived?					
347	17.5.2	Does the duration of archiving correspond to the applicable legislation (Product Liability 85/374/EC Article 11) and internal regulations?					
348	17.5.3 / 17.5.4	Are the stored / saved documents (in paper or electronic form) legible and secured?					
349	17.5.5	Is backup data stored at regular intervals and is the data kept in a separate and secure location?					

Reference:

IKW Cosmetics GMP based on ISO 22716

Website References:

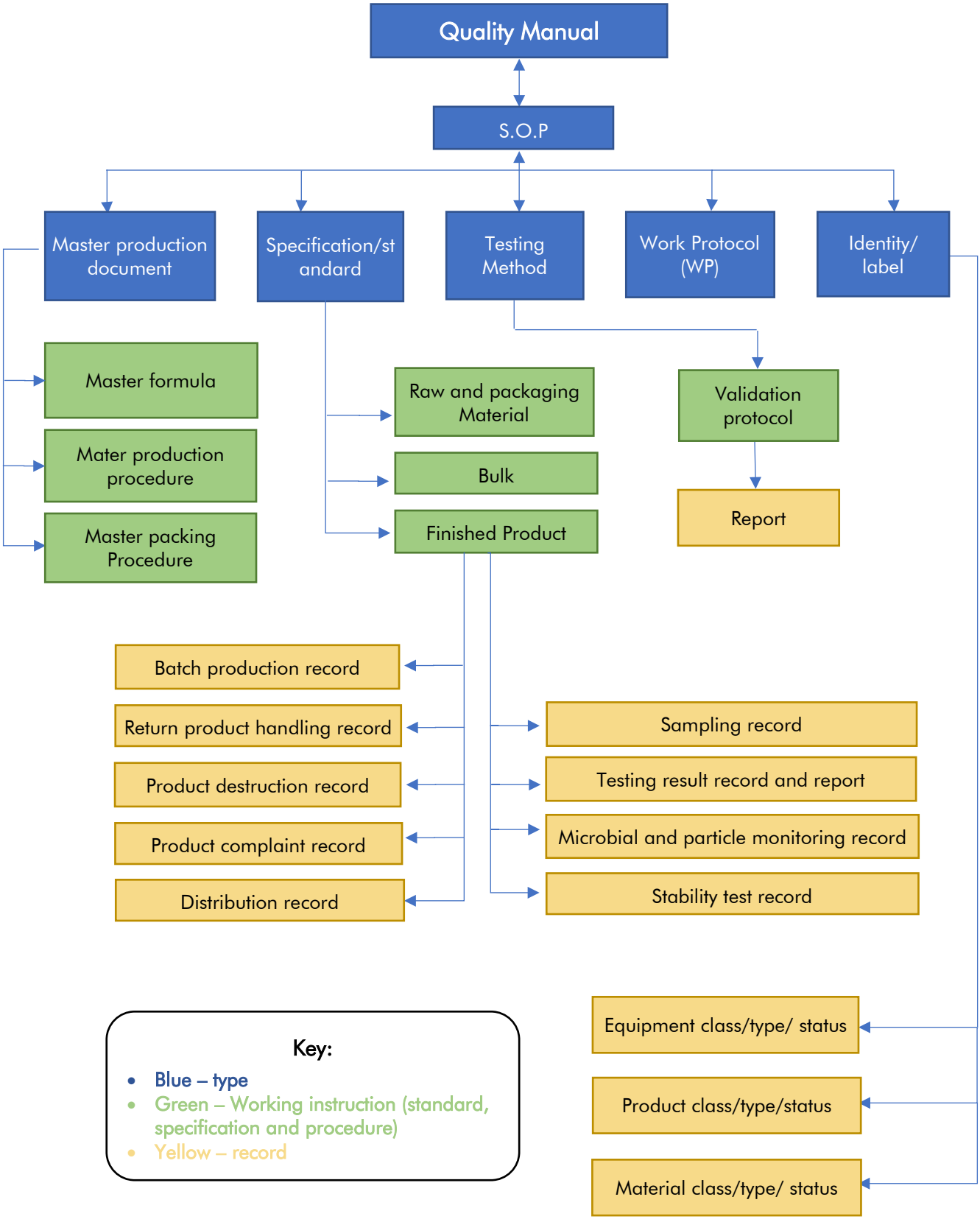
A WHO guide to good manufacturing practice (GMP) requirements
https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1
Last viewed 22nd August 2021

ASEAN Cosmetic GMP Team: https://asean.org/storage/2012/10/ASEAN-TMHS-GMP-Training-Chapter-2-Personnel-FD1.pdf
Last viewed 22nd August 2021

Northern Ireland Blood Transfusion Service SOP:
https://hscbusiness.hscni.net/pdf/Controls_of_standard_procedure_related_to_SOPs.pdf
Last viewed 22nd August 2021

Archiving of Essential Documents - template – Oxford: https://www.ouh.nhs.uk › *researchers* › *template-...*

17.346. Annex 1: Flowchart - Types of GMP documents



17.2. SOP 346 - Document preparation, maintenance and change control of master documents

Logo	**Standard format for SOP:** Preparation of documents and quality documentation system, document preparation, maintenance and change control of master documentation. Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

[Indicate the purpose of the SOP here. Ensure that for each SOP the purpose statement is clearly understandable, implementable in especially the SME environment and succint to achieve traceability and evidence in the fulfilment of good manufacturing practices.]

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

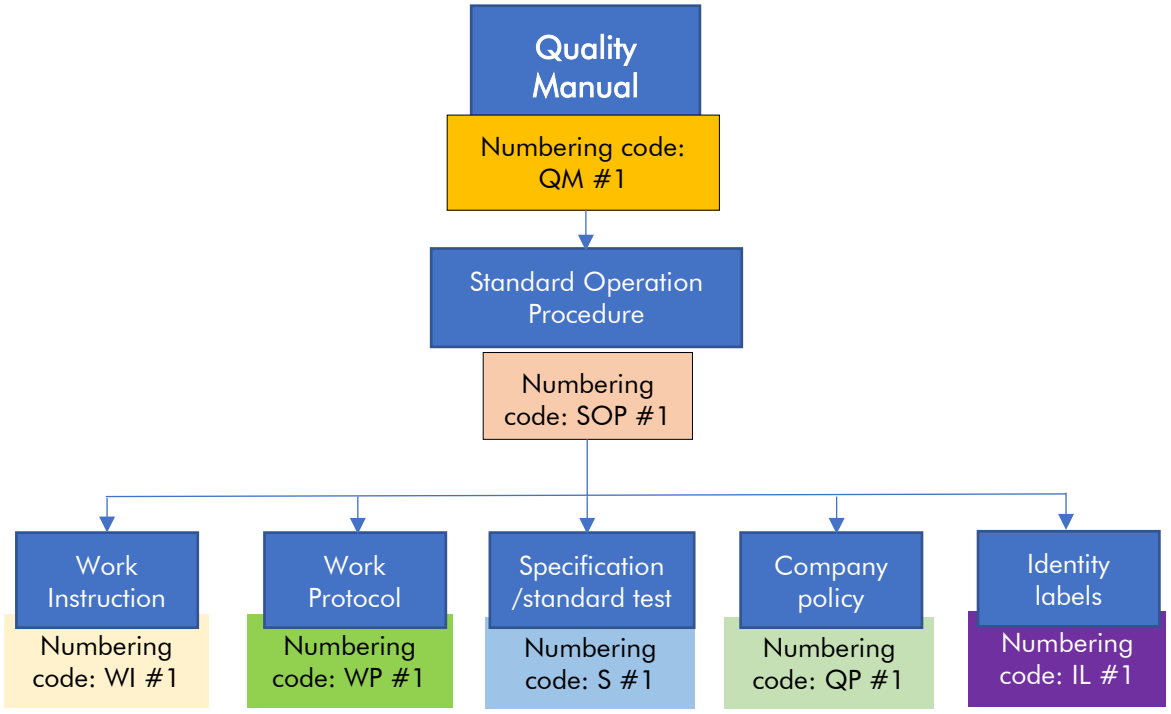
Responsibility:

Quality Control Officer

Material and Equipment:

Procedure:

17. 346. Annex 2: Flow chart - Documentation system



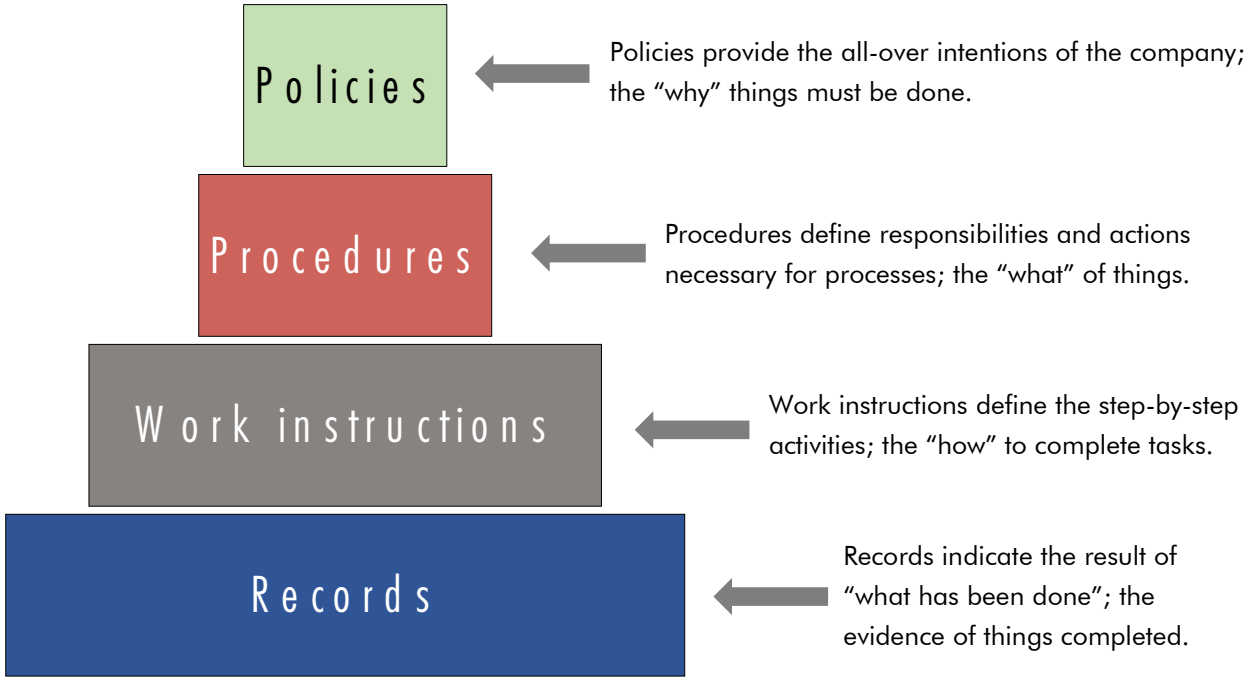


Figure 3 – Different tiers of documents in a GMP environment

The organisation should adopt and in-house format for its documents and/or develop a template. See Annex C for an example. The first page should have a footer with the designation and signature of the person preparing, approving, and authorising the document along with the dates. Any alteration made to a document should permit reading of the original information. Computer stored documents should be safeguarded from virus and data loss, and against unauthorised data access.

This SOP details the instructions and procedure for a quality documentation system as follows:

1. Documentation structure (e.g. Quality Manual, Quality Procedures, Instructions and Records)
2. Format requirement for different types of documents
3. Numbering and reference system
4. Handling of controlled and uncontrolled documents
5. Handling of obsolete versions
6. Preparation, approval, distribution of documents
7. Review and change control
8. Documentation controller
9. Storage of master documents
10. Retention period for records
11. List of controlled documents

1. Documentation structure

1.1. Quality Manual

1.1.1. A Quality Manual contains details of the company's commitments to quality and defines the quality system of the organisation. The Quality Manual may include attached documents such as SOPs.

1.1.2. A Quality System indicates the establishment of a compatible structure that covers the procedures, processes and resources of a company.

1.1.3. The Quality Manual contains clear and documented "Quality Policy Statements" (QPS). This QPS includes the commitment of the company to the production of safe products of high quality.

1.1.4. The QPS includes the company's responsibility to its clientele.

1.1.5. The Senior Manager is held responsible for committing to QPS and is tasked with signing off the policy statement.

1.1.6. The QPS is implemented and understood by all key personnel and supervisory staff within the company.

1.1.7. The QPS is communicated to all staff in the company and reviewed regularly.

1.1.8. Company management is responsible for drawing up the QPS and ensures that:

- The QPS is suitable for the requirements of the organisation and its clients.
- The QPS incorporates and demonstrates the commitment to meeting the requirements and ensures frequent reviewing and revision.
- The QPS provides an outline for the set up and reviewing of quality objectives.
- It must be ensured that the QPS is communicated, understood and executed throughout the organisation.

1.1.9. The QPS for the company is defined as **a formal declaration** that explains how the company conducts its business in order to achieve product quality.

1.1.10. The QPS explains the organisational structure and job descriptions of key personnel.

1.1.11. The Quality Manual is made readily available to relevant personnel.

1.1.12. The company management is held responsible for periodical review of its quality system and shall ensure its constant effectiveness and suitability.

1.2. Quality Manual instruction:

1.2.1. The Quality Manual (QM) is structured according to the prescribed ISO format and includes the GMP principles for 22716 standard.

1.2.2. The QM comprises a title, scope and revision history.

1.2.3. The title describes the company sites and the scope describes the operations which are covered in the QM.

1.2.4. The QM includes the QPS as stated above (section 1.1.4).

1.2.5. Senior management appoints a management representative to be tasked with the implementation of the QM. The management representative represents the management authority and monitors the system.

1.2.6. The key objective of the QM describes the company's organisational structure, authority, responsibilities and functions.

1.2.7. The management representative is charged with the control of the QM as follows:

- Review and revision
- Distribution to the appropriated members
- Content and amendment

1.2.8. The QM shall contain information and instructions relevant to the following:

1. Scope
2. Terms and definitions
3. Personnel
4. Premises
5. Equipment
6. Raw materials and packaging materials
7. Production
8. Finished products
9. Quality Control laboratory
10. Treatment of products that are out of specification
11. Waste
12. Subcontracting services and contract manufacturing services
13. Deviations
14. Complaints and Recalls
15. Change Control
16. Internal Audit
17. Documentation

1.2.9. Each topic contains references at the end of the IKW checklist provided in the form of websites.

1.2.10. The QM only contains the management policies which govern the application of procedures.

1.2.11. The QM does not include technical procedures unless it is necessary. All procedures are referred to specifically by title and reference number, when appropriate.

1.2.12. The QM shall include a Quick Checklist for all GMP requirements on each topic listed in (section 1.2.8) above.

1.2.13. The QM shall contain the company QPS on the following:

- Criteria for staff involved in the manufacturing activities
- Assuring staff's competency in their work
- Assuring staff's understanding of procedures, work instruction, GMP principles, etc.
- Assuring that there is no ambiguity of staff's roles and responsibilities
- Staff resources allocation
- Authority of QC and Production

1.3. Structure and format of SOP documents:

1.3.1. SOPs are to be process oriented and describe the steps of procedure for a specified activity.

1.3.2. SOPs describe specified activities in support of the QM and are removable attachments inside the QM.

1.3.3. SOPs are utilised by staff to explain the general description on specific processes and provide systematic action to ensure that the quality of the product is maintained.

1.3.4. The QA person in charge of drafting SOPs shall include the necessary "reference documents" needed for proper implementation.

1.3.5. Structure and format of work instruction:

1.3.6. The work instruction is task oriented with detailed instructions. For example, in the case of equipment operating instructions, the work instruction is usually provided by the equipment manufacturer in the form of a leaflet, manual or guidebook. If the equipment manufacturer has not provided an instruction manual, then your company must provide one in either hardcopy format or via helpful videos,

illustrations etc.

1.3.7. The work instruction shall be designed and utilised to explain a special task, method or technique which needs be done to achieve the targeted quality.

1.3.8. Work instructions are kept separately from the QM.

2. Format requirement for different types of documents:

2.1. [NB: there is no specified "best format" for a documentation system.].

2.2. Based on the cosmetic manufacturer's documentation system, all quality documents shall be structured in any of the following formats depending on the type of documentation:

- Flowchart
- Narrative
- Combination of both narrative and flowchart
- Electronic

2.3. Narrative documents:

2.3.1. Narrative documents are used for detailing instructions of specified procedures and contain policy references, the objective, the scope, document references, the staff responsible, other necessary records where applicable and the detailed instructions.

2.3.2. The instructions in narrative documents are clear and unambiguous for staff to follow correctly and easily.

2.4. Flowchart document:

2.4.1. The flowchart is used when a schematic representation is required.

2.4.2. The flowchart describes the flow of processes in a targeted activity.

2.4.3. The flowchart is designed in such a way to ensure clarity and should be easily understood.

2.5. Combination document:

2.5.1. Some narrative documents may include a flowchart to support the instructions, this may also be attached and referred to in the instructions.

2.6. Electronic Document:

2.6.1. Only specified documents may be handled electronically.

2.6.2. Only authorised personnel are permitted to enter or modify electronic data for processing methods.

2.6.3. All alterations or deletions are kept on record with restricted access via password or other means.

2.6.4. Any alterations or entries to critical data/documents are checked autonomously.

2.6.5. In the case of master documents, clear copies may be printed for use with individual batches only when authorisation has been given.

3. Numbering and Reference system

3.1. Every document should have a number from the Control Division.

3.2. A document numbering system should be generated to make for good understanding on saving and control of the document.

3.3. There are also the identification systems or codes which can be defined to number and track both information and documents. These are SOP numbers, equipment numbers, form numbers, receiving codes, and batch/lot numbers.

3.4. These numbering systems should be designed in such a way that procedures, processes and materials can be traced throughout the data records.

3.5. For this quality manual the SOPs shall be numbered according to the corresponding number of the GMP requirement which can be found in the IKW ISO 22716 checklist.

4. Handling of controlled and uncontrolled documents

4.1. All documents shall be authorised and dated.

4.2. Prior to implementation, all documents (especially SOPs) shall be approved, signed and dated by the delegated authority within the company.

4.3. No document shall be amended or altered without authorisation.

4.4. All document records shall be kept up to date and must be completed in accordance with the process.

4.5. Documents shall be distributed in accordance with a distribution list and must be recorded.

4.6. A list of current documents, centralised-controlled, should be in place.
4.7. Any outdated documents shall be taken from users according to the distribution list, annotated as "obsolete "and archived.
4.8. The company staff shall only make use of the updated or latest version of a document.

5. If there has been no previous file, a new file shall be created. When a new file is created the following shall be followed:
   5.1. allocate classification, titling and indexing to the record
   5.2. allocate file number
   5.3. physically construct the file
   5.4. register the file on the records management system.
6. Handling of obsolete versions of documents
   6.1. Any obsolete documents shall be taken from users according to the distribution list, annotated as "obsolete" and archived.
   6.2. The company staff shall only make use of the updated or latest version of documents
7. Preparation, Approval, Distribution of documents:
   7.1. QA department shall ensure that a list for the distribution of documents is readily available.
   7.2. The documents are printed and distributed to the relevant parties according to the distribution list provided.
   7.3. Only the latest or most recent version of documents may be distributed and used.
   7.4. The extent of documentation will vary according to the size of the plant, the number of products and the number of personnel handling products. In a small scale or micro scale enterprise, there may be few people and few products. The level of documentation will be low. For example, if there only one machine for mixing ingredients and there is only one product and one operator, then the procedure can be straight forward.
      - If there is more than one person who operates the machine, there is a need for writing the procedure so that different operators can be consistent.
      - There are different types of documents and include procedures, instructions, specifications, protocols, reports, methods, and records appropriate to the activities.
      - The tiers of documentation in a GMP environment are represented in Figure 3. The documents may be grouped into manual e.g., policies manual, procedure manual and records.
   7.5. The QA members shall be responsible for the distribution of documents.
   7.6. Prior to distribution, the QA and Production department shall receive the main or "Quality Manual" document which will include supporting documents as attachments/annexures.
   7.7. Thereafter, the QA and Production department shall distribute the supporting documents respectively.
8. Documentation controller
   8.1. Documents should be dated and authorised as follows:
      - Approved, signed and dated by the staff authorised to do so.
      - No document should be changed without authorisation.
   8.2. All document records should be completed as the process moves forward.
   8.3. A distribution list documenting the distribution of the documents should be kept.
   8.4. It is essential that documents are completed as the process moves forward. Inspectors should examine documents in progress for signs of either pre-process completion or post-process completion.
   8.5. Any alteration or amendment to a document should be signed and dated; the alteration or amendment should not override the original information. Where necessary, the reason for the alteration or amendment should be recorded. An example, the error of signing the documentation for flaming lipstick products before the product is packed into its tube containers.

Obsolete documentation:

Obsolete documents should be:

- Removed from current use, based on the distribution list
- Marked "obsolete" and archived

9. Storage of Master Documents:

9.1. All essential documents shall be stored in a manner and location which ensures integrity and readability.
9.2. All essential documents shall be stored in a manner and location which ensures access to authorised individuals only.
9.3. Documents shall be archived in alphabetical or chronological order. This includes electronic files and hardcopy files.
9.4. The filing system implemented needs to be efficient and comprehensible.
9.5. The administrator/ secretary shall keep a record of all transfers of ownership of documents.
9.6. Once the ownership transfer document has been processed, the company shall no longer be held responsible for the archiving of that particular document.
9.7. Only delegated individuals shall be granted access to archived documents.
9.8. All media used to archive documents, whether electronic or otherwise, shall be such that the file maintains its original format, remains complete and readable throughout the duration of it's retention.

10. Retention Period for Records:
10.1. All essential documents shall be retained for a period of at least 5 years (in accordance to the local Legislation Act).

Definitions:

Reference documents:

17.346. Annex 1: Flowchart for Types of GMP documents

17.3. SOP 347 - Document distribution and control

17.5. SOP 360 – Document Retrieval and Archiving

7.3. SOP 204 - Batch numbering and labelling system

Logo	**Standard format for SOP:** Batch numbering and labelling system Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To laydown a labelling system that will comply with GMP requirements for labelling. It should be clear, identifiable and should be able to ensure the traceability of all cosmetic products and materials of [company name]

Scope:

This SOP provides instructions of a labelling system that covers all labelling requirements for all labels used in class 1 and class 2.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

Quality Control Department shall be responsible for the issuance of all Class 2 labels and shall ensure that Class 1 labels have met national regulations where applicable.

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Labelling system
   - 1.1. For production purposes, the cosmetic manufacturing company is required to have a labelling system in place which can be used to identify the status of materials, products, equipment and laboratory reagents. The cosmetic facility itself must also produce labels for the demarcated and restricted areas within the facility as well as warning labels.
   - 1.2. The labelling system shall be made up in two classes as follows:
     - Class 1 labels for finished goods [insert label color code].
     - Class 2 labels used within the factory to control progress [insert label color code].
   - 1.3. Class 1 labels must meet the GMP 22716 standard regulatory authority requirements as indicated in the marketing authorisation prior to use. All finished product labels need to meet the national requirement.

1.4. Class 2 is used for internal labelling. Class 2 labelling shall be overseen and regulated by the QC department.

1.5. The QC personnel shall be responsible for the issuance of status labelling based on when a material/product/batch has been approved or rejected.

1.6. The cosmetic manufacturer shall appoint a responsible individual from the QC or production department who will sign off labels stating that equipment is available for use/clean.

2. Class 2 labels indicating the status of a batch/product or material shall be color coded as follows:

- Quarantine – [insert color code]
- Accepted – [insert color code]
- Rejected – [insert color code]
- Cleaned – [insert color code]
- Soiled – [insert color code]

2.1. All labels should be clear and legible. The QC department shall be in charge of assigning labels for all containers, which includes but is not exclusive to:

- Starting materials
- Intermediate materials
- Finished products
- Sample labels
- Sampled (already sampled)
- Process equipment
- Labels for all areas used for production (storage areas, quarantine areas, testing areas, etc.)

2.2. Class 2 labels include the following:

No.	Label Type:	Colour code	Reference Document
1.	Raw material tags	[insert colour code]	
2.	Quarantine status label - release/reject	[insert colour code]	
3.	Storage area identification labels	[insert colour code]	
4.	Biohazard / danger materials	[insert colour code]	
5.	Restricted access labels	[insert colour code]	
6.	Equipment	[insert colour code]	
8.	Equipment cleaned/waiting for cleaning labels	[insert colour code]	
9.	Process intermediate labels	[insert colour code]	
10.	Final product labels	[insert colour code]	

2.3. All raw materials/bulk materials and finished product labels should have a product number or identification code to enable it to be tracked and identified by production staff.

Definitions:

Reference documents:

17.3. SOP 360 – Document Retrieval and Archiving

17.5. SOP 360 - Document retrieval and archiving

Logo	**Standard format for SOP:** Document retrieval and archiving Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

The purpose of this SOP is to provide clear instructions for archiving documents relevant to cosmetics production [insert company title], and which may be retrieved by inspectors, auditors and other authorised personnel only.

Scope:

This SOP applies to the QA department, QC department, and the production department of [insert company title] in relation to cosmetic production.

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The QA Senior Manager/Head

QC Senior Manager/Head

Production Senior Manager/Head

Secretary/ Administrator for the various company departments

Material and equipment:

WHAT: [What is needed to perform the procedure. The list should be complete and specific.]

Procedure:

1. Detailed Procedure For Document Archiving:
   1.1. What to archive:

The company shall ensure that all essential documents are archived, including but not limited to the following:

- Trial Master files
- Source documents
- Company contracts and agreements

1.2. Archiving period for essential documents:

All essential documents shall be archived for a period of at least 5 years (i.e. in accordance to the local Legislation Act).

1.3. Archiving process:

1.3.1. Follow the instructions for document storage as prescribed in SOP 346 section 9.

1.3.2. All essential documents shall be stored in a manner and location that will preserve the integrity and readability.

1.3.3. All essential documents shall be stored in such a manner and location that will ensure access to authorised personnel only.

1.3.4. Documents shall be archived in alphabetical or chronological order in accordance with the title and number of the file. This includes electronic and hardcopy files.

1.3.5. The filing system needs to be efficient and understood by all staff in each department.

1.3.6. The administrator/ secretary shall keep a record of transfers of ownership of documents.

1.3.7. Once the ownership transfer document has been processed, the company shall no longer be held responsible for the archiving of that particular document.

1.3.8. Only delegated individuals shall be granted access to archived documents.

1.3.9. All media used to archive documents, including electronic systems or otherwise, shall be such that the file maintains its original format, remains complete and readable throughout the duration of its retention.

1.3.10. The document archiving system must be compiled as such that any alteration or amendment of records are traceable.

1.3.11. All TMF and SD(s) are required to be accurate and legible.

NB: it is important to note that while there is no specific legislation for the labelling of archived documents, it is still important to have a decent labelling system in place. This can be achieved by attaching a study title, reference number, date archived and date to be destroyed on each box or drawer containing essential documents.

1.4. Where to archive:

1.4.1. All essential documents shall be archived in a suitable storage facility or secured filing cabinet (consider fire protection without water sprinkler systems, water protection, humid conditions, pests etc). The storage facility or secured filing cabinet should only be accessible to authorised personnel.

1.4.2. It is possible to use an external archive site if necessary.

2. Detailed Procedure for Document Retrieval:

2.1. Essential documents may only be retrieved by authorised personnel. These include :

- inspectors
- auditors,
- a government official with a valid warrant
- authorised company staff [include titles of your company's authorised staff here]

2.2. Any essential document which has exceeded the 5-year archive period may only be destroyed once it has been released as such by the delegated authority.

2.3. Prior to the retrieval of any essential document a "Request for Retrieval of Document Form" shall be completed, signed and dated.

2.4. Retrieval of any essential document without complete processing of a "Request for Retrieval of Document Form" is strictly prohibited. The departmental administrator or secretary however, is allowed to retrieve documents for administrative purposes.

2.5. The departmental administrator/ secretary shall retrieve the archived document(s) and will return the file back to its original place immediately after use.

2.6. The departmental administrator/ secretary shall be held responsible for the maintenance of the Register Log Sheet for Document Retrieval.

2.7. The Register Log Sheet for Document Retrieval shall provide the following information:

- File Number
- File name
- Designation of individual making a request for retrieval
- Signature of individual making a request for retrieval
- Date of approval of request
- Date and time of retrieval
- Name and signature of relevant administrator/ secretary
- Date and time when the file is returned

2.8. The administrator/secretary shall keep a record with signature and date when the file has been returned

Definitions:

TRM- Trial Master File: The TRM is a file that contains all important company documents.

DS - Source Documents: DS refers to the original copy of the document, data, or record.

Reference documents:

17.3. SOP 347 - Document distribution and control

17.2. SOP 346 - Document preparation, maintenance and change control of master documentation

17.360.Annex 1:Form - Document request form

[Company Header]

Company title: _____

Document Request Form

Date: _____

Request: _____

Title: _____

Department: _____

Description of document(s): _____

_____

_____

_____

I have requested:

☐ A copy of the document _____ time request submitted.

☐ The original document _____ time request delivered.

Signature of Requestor **Signature of Records Staff**

_____ _____

Request form number: _____ Authorised by: _____

Authorisation initial and signature: _____

17.360. Annex 2: Form - Archive register log sheet

Archives register sheet

Administrator name: _____ Signature: _____

Date: _____

File no.:	File name:	Requestor:	Designation:	Approval		Retrieval			File returned	
				Date:	Time:	Date:	Time:	Signature:	Date	Time

17.3. SOP 347 - Document distribution and control

Logo	**Standard format for SOP:** Document distribution and control Department: _____ Policy No: _____

Company header: _____

Policy: _____

Name of area: _____ Page: _____ of_____

SOP number: _____ Title: _____

Revision number: _____

Written by: _____ Edited by: _____

Authorisation signature: _____ Department: _____Date: _____

Effective date: _____ Replaces: _____

Purpose:

To lay down the procedure for distribution and control of documentation.

Scope:

WHEN: [Indicate when this procedure needs to be performed.]

WHERE: [Indicate where this procedure applies.]

Responsibility:

The Quality Manager shall keep track of staff members who need specific SOP's and will keep record of who has read and understood the documents.

QA chemist/QA officer

Accountability:

Head of Quality Assurance

Procedure:

1. Distribution:
   - 1.1. QA department provides a list for the distribution of documents.
   - 1.2. The documents are printed and distributed to all parties according to the distribution list.
   - 1.3. Only the latest or most recent version of a document may be distributed and used.
   - 1.4. The QC members shall be responsible for the distribution of documents.
   - 1.5. Prior to distribution, the QC and Production Department shall receive the main or "Quality Manual" document which will include supporting documents as attachments/annexures.
   - 1.6. Thereafter the QC and Production department shall distribute the supporting documents as required.
2. Document pre-distribution authorisation
   - 2.1. In completion of the final draft of the procedure on _____. [insert title of SOP] the author and approver are required to approve the document on _____. [insert title of SOP].
   - 2.2. On receipt of all [insert title of SOP] approvals the Document Control Officer will issue a hard copy of the SOP

and will print and distribute it to the relevant department for approval and signature. For the purpose of clarity, the front page will be used to sign off SOPs. The author and approver must sign the front page of the hard copy document and confirm that the content and numbering of the document is accurate and return the document to the Document Control Officer.

2.3. The approver, normally the department manager/section head or deputy, is responsible for ensuring the SOP and the related forms meet the relevant requirements of GMP cosmetics 22716 and any other relevant legislation processes.

2.4. The department manager/section head ensures that any person delegated to perform SOP preparation is trained to do so. Where supervisors or managers perform this function they must ensure that the document accurately describes the procedures as they are routinely performed.

2.5. All quality assurance SOPs relevant to the quality system must be authorised by the Quality Manager for Regulatory Affairs and the Compliance Manager.

2.6. All procedures developed by senior management must be authorised by the Chief Executive.

2.7. Departmental managers/section heads are responsible for ensuring that unused or obsolete versions of drafted document forms in their department are destroyed and that any master drafted documents form in the department is updated with the current version of the document.

3. Documentation control

3.1. Documents should be dated and authorised

- Approved, signed and dated by delegated authorised persons.
- No document should be changed without authorisation.

3.2. All document records should be completed as the process moves ahead.

3.3. A distribution list of the distribution of all documents should be kept.

3.4. It is essential that documents are completed as the process moves ahead. Inspectors should examine documents in progress for signs of either pre-process completion or post-process completion.

3.5. Any alteration or amendment to a document should be signed and dated; the alteration or amendment should retain the original information. Where necessary, the reason for the alteration or amendment should be recorded. An example, the error of signing the documentation for flaming lipstick products before the product is packed into its tube containers.

3.6. All obsolete documentation shall be retrieved from the users based on the distribution list.

3.7. All obsolete documentation shall be marked "obsolete" prior to being archived.

3.8. Only updated versions of documents may be distributed.

3.9. All essential documents shall be deemed legal authentic data of [company title] and shall be controlled as such. (this is considered an essential component of a company's quality system).

3.10. All activities related to cosmetic manufacturing shall be documented as per the requirement of GMP.

3.11. Alterations made to documents shall only be done by qualified and experienced staff who are familiar with the department.

3.12. All documents on new products or processes shall be prepared by the relevant department.

3.13. The head of each department shall be responsible for the preparation and review of new or modified documentation as follows:

- Product specification
- Product master formula record
- Batch processing record manual
- Company/ manufacturing protocols

4. Routine review

4.1. Any alterations to procedures within a SOP shall be updated immediately.

4.2. The maximum duration for a SOP as of the date of issue, shall be two years unless it is stipulated otherwise by a relevant regulatory body for annual review. If a period of less than two years is necessary, the SOP author/approver shall notify the relevant QA members.

4.3. The head of department shall be responsible for review and tracking of any SOPs within their area.

4.4. To ensure efficiency in the document review system, a document should have been visited or reviewed within 23 months of issue. After that date, any non-review- or visit should be reported to the manager.

Definitions:

Reference documents:

17.346. Annex 1: Flowchart for Types of GMP documents

17.2. SOP 346 - Document preparation, maintenance and change control of master documentation

17.5. SOP 360 - Document recovery (archiving)