APEXGLOBAL

QUALITY

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COS-GMP

COSMETICS GOOD MANUFACTURING PRACTICES

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VERSION

Version	Affective date	Details of changes
1.0	**01/05/2025**	First release

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1.0

PURPOSE

1.0 PURPOSE

The **COS-GMP** standard is designed for organisation's seeking to establish a formal, documented Good Manufacturing Practices Management System (GMP-MS) for cosmetic product manufacturing, aligning with the Generals of ISO 22716 Cosmetics – Good Manufacturing Practices (GMP) – Requirements. Organisation's may choose to implement this standard to meet customer expectations or to develop a GMP framework that supports continuous improvement.

COS-GMP was developed as a comprehensive re-imagining of ISO 22716, with the following key objectives:

- Enhancing clarity and understanding of the requirements.
- Eliminating redundant text.
- Addressing commonly misinterpreted aspects.
- Integrating essential components such as risk management, senior management commitment, and preventative action strategies.
- Refining the numbering and structural organisation of sections and clauses.
- Ensuring applicability to service provisions (outsourcing and subcontracting).
- Simplifying internal and external auditing processes for compliance.
- Broadening the scope to include categories of product application such as pet care which is excluded from ISO 22716:2007

COS-GMP includes the basic requirements of ISO 22716 in a clause-based format without using original ISO 22716 language, avoiding copyright or trademark issues.

Any sections labeled as "Notes" do not impose mandatory requirements but instead serve to clarify concepts for better understanding. To facilitate easy identification of specific evidential requirements, the standard employs a color-coded system:

- Green – Documents
- Blue – Records
- Orange – Specifications
- Red – Risk assessments
- Purple – Trending

Regardless of whether a clause explicitly references documents or records, compliance with the standard assumes that appropriate evidence is available for each requirement.

All stock items produced within the scope of this standard shall be produced in accordance with local and applicable legislation.

This standard acknowledges that quality is everyone's responsibility and should not be restricted to a department. This standard refers to the pre-exiting quality department henceforth as **Technical Compliance**.

In addition to the above, this standard recognizes that other good manufacturing practices standards for cosmetics are only applicable to human contact products, which excludes a large number of potential stakeholders. This standard applies its requirements into categories that allow a larger number of organisations to introduce robust and effective controls, where they would not have done otherwise. The categories are as follows:

Category Code	Name	Notes
01	**RAW MATERIALS DESTINED FOR COSMETIC PRODUCTS**	Products that are concidered raw materials but are intended to be used in the cosmetic products
02	**PACKAGING MATERIALS DESTINED FOR COSMETIC PRODUCTS**	Products that are concidered packaging materials but are intended to be used in the cosmetic proucts
03	**CHEMICAL PERSONAL CARE COSMETICS**	Cosmetics in the form of chemicals such as liquids, powders
04	**PET CARE COSMETICS**	Finished products destined for animal use
05	**TEXTILE PERSONAL CARE COSMETICS**	Cosmetics in the form of textiles such as personal wipes

2.0

REFERENCES

2.0 REFERENCES

- AGQ COS-GMP 002 – Implementation – A guide on how to implement the standard
- ISO 22716:2007 Good Manufacturing Practices
- ISO 22715:2006 Good Manufacturing Practices - Labelling
- BRCGS Consumer Products 4 Personal Care & Household
- The Codex Alimentarius Commission's HACCP guidelines
- FDA - Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics
- Chemlinked - China’s GMP Standard

3.0
DOCUMENTATION
(MANAGEMENT ELEMENT)

3.0 DOCUMENTATION

3.1 GENERAL

3.1.1 The organisation shall define controls for documentation through a **documented procedure**, this shall include:
- a list of all controlled documents with the latest version number
- methods for creating, identifying and authorizing controlled documents
- **records** of reasons for changes to documents
- a system for replacing updated documents and informing relevant personnel

3.1.2 Where documents and **records** are in electronic form these shall be:
- stored securely
- backed up
- be easily accessible to ensure traceability.

3.2 CONTROL OF DOCUMENTS

3.2.1 Documents shall be defined and describe, with appropriate detail, the operations to be carried out, precautions to be taken and measures to be applied in all activities.

3.2.2 Documents shall contain, at minimum;
- a title, which should be unambiguous
- a unique reference
- a version
- an author
- the date of approval.

3.2.3 Documents shall be:
- written in a legible and comprehensive way;
- approved and dated by authorized persons before being used;
- prepared, updated, withdrawn, distributed, classified;
- referenced to ensure that obsolete documents are not used;
- accessible to appropriate personnel;
- removed from the job area and destroyed if they are outdated.

3.2.4 Documents shall be updated, when necessary, and the version number indicated. The reason for each revision shall be retained and previous versions archived.

3.2.5 The duration of archiving original documents shall be defined according to applicable legislation and regulations.

3.2.6 The storage of archived documents shall be properly secure.

3.2.7 Documents may be archived as either electronic or hard-copies and their legibility shall be ensured.

3.3 CONTROL OF RECORDS

3.3.1 **Records** shall be legible, appropriately authorised, retained in good condition, and retrievable.

3.3.2 **Records** which require the entry of handwritten data shall:
- indicate what is to be entered;
- be written legibly with permanent ink;
- be approved and dated;
- be corrected, if needed, maintaining legibility, authorised and justification for the alteration shall be

recorded.
- not contain any ambiguous declaration such as the use of ticks where ticks are not completely obvious
- not contain any blank fields where “NA” could be used to denote not applicable or other similar language

NOTE 1 The use of correction fluid is not acceptable as this makes the initial information illegible

3.3.3 The organisation shall **document** the retention period for **records** related to the product's usable life, intended use, and customer or legal requirements.

3.4 ELECTRONIC DOCUMENTATION

3.4.1 The organisation shall define controls for software validation through a **documented procedure** for any and all software used to support the GMP management system. The validation plan shall be proportionate to the **risk** associated with the software. At minimum, the validation plan shall include:
- sufficient protection shall be in place to ensure correct entry of the data
- a back-up system shall be created to ensure that the original data can be retrieved in the event of file alteration, corruption or deletion
- adequate protection shall be in place to prevent unauthorised access to the data
- procedures shall be established outlining the issue, cancellation or amendment of authorisation
- procedures shall also be established defining the action to be taken in the event of system failure or -breakdown
- all safeguards, back-up systems and procedures shall be regularly checked and updated as necessary.

3.4.2 Any electronic system that is used to control critical operations or documentation such as documentation storage, stock quarantine / release status shall be restricted to allow access and ‘change control’ only by authorised personnel.

3.4.3 The organisation shall maintain a signed, **documented** contract with subcontractors defining how it manages IT system activities, where applicable.

3.4.4 Adequate alternative arrangements shall be available for systems which need to be operated in the event of a failure or breakdown including:
- backup and protection of electronic **Records**;
- Alternative systems in the event of the IT system going offline.

4.0
RISK CONTROL
(MANAGEMENT ELEMENT)

4.0 RISK CONTROL

4.1 PRODUCT CONTAMINATION CONTROL

4.1.1 GENERAL

4.1.1.1 All practicable steps shall be taken to identify, eliminate, avoid or minimise the **risk** of foreign-body or chemical contamination.

4.1.2 HAZARD ANALYSIS RISK ASSESSMENT (HARA)

4.1.2.1 The organisation shall define the controls for hazard analysis risk assessment (HARA) in a **documented procedure** with **records** maintained to ensure that all hazards to stock item safety and legality are identified, and appropriate controls established.

4.1.2.2 A multi-disciplinary team shall be assembled to conduct the hazard analysis. The team shall include individuals with expertise in relevant areas such as production, Technical Compliance, engineering, and regulatory compliance. The team shall be responsible for identifying hazards, assessing risks, and implementing control measures.

4.1.2.3 A clear product description shall be **documented**, detailing key characteristics such as:
- Product name and intended use
- Key ingredients or components
- Storage and handling requirements
- Shelf life and any special conditions for maintaining product safety.

4.1.2.4 The organisation shall develop a process flow diagram outlining all stages of stock item handling, from receipt of raw materials through processing, storage, and distribution, including rework and returns. The flow diagram shall be verified for accuracy and updated as necessary.

4.1.2.5 A hazard analysis shall be conducted for each step of the process flow to identify potential biological, chemical, physical, and allergenic hazards. Each identified hazard shall be assessed for:
- Likelihood of occurrence
- Severity of impact
- Necessary control measures to prevent, eliminate, or reduce the hazard to an acceptable level.

4.1.2.6 The HARA process shall include the identification of:
- Quality Control Points (QCPs): Control points addressing organisation-specific high-risk aspects within the GMP management system.
- Critical Control Points (CCPs): Control points addressing critical hazards that could result in product safety risks.

4.1.2.7 For each identified hazard requiring control, a logical approach shall be used to determine if it qualifies as a Critical Control Point (CCP). This process may be facilitated through a decision tree.

NOTE 1 Critical control measures are those necessary to prevent, eliminate, or reduce a product safety hazard to an acceptable level.

4.1.2.8 Each Critical Control Point (CCP) shall have clearly defined:
- Control measures
- Critical limits
- Monitoring activities
- Corrective actions.

4.1.2.9 For each identified hazard requiring control, a **risk assessment** shall be used to determine if it qualifies as a Quality Control Point (QCP), based on internal requirements.

NOTE 1 Quality control measures are those necessary to prevent, eliminate, or reduce a product hazard to an acceptable level within the organisation's internal quality framework.

4.1.2.10 Each Quality Control Point (QCP) shall have clearly defined:
- Control measures
- Limits
- Monitoring activities
- Corrective actions.

4.1.2.11 The organisation shall implement procedures to monitor the effectiveness of hazard controls. This shall include:
- Routine inspections and testing
- Periodic verification of process controls
- Review of hazard analysis findings to ensure ongoing effectiveness.

4.1.2.12 All activities related to hazard analysis and **risk assessment** shall be **documented** and maintained. **Records** shall include:
- Team meeting minutes and decisions
- Hazard analysis reports
- Process flow diagrams
- Control measure implementation **records**
- Verification and validation reports.

4.1.3 CHEMICAL CONTROL

4.1.3.1 A properly maintained consumables register shall be established for chemicals and maintenance materials, including lubricants, greases, and oils, to **document** their **risk** and usage. Safety data sheets shall serve as justification and be preserved as **documented** evidence. This register shall include, as a minimum:
- a list of approved chemicals for purchase
- availability of safety data sheets and specifications
- avoidance of strongly scented products
- the labelling and/or identification of containers of chemicals at all times

designated storage area with access restricted to authorised personnel

NOTE 1 This will be referred through the standard as AMR for Approved Materials Register and includes cleaning chemicals as well as engineering materials such as lubricants, oils and greases

4.1.4 FOREIGN BODY CONTROL

4.1.4.1 Based on **risk**, **documented procedures** shall be implemented to identify, control and manage any potential risks from foreign body contamination.

4.1.4.2 There shall be no uncontrolled foreign body contamination risks within the GMP control zones that create a risk to product safety, legality, or quality.

4.1.5 GLASS AND BRITTLE MATERIALS CONTROL

4.1.5.1 Glass or brittle materials, with the exceptions of stock item materials, that pose a potential product contamination shall be controlled and **recorded** on a register that includes the item along with their respective location, quantity, type of material (glass, plastic, ceramic etc...), current condition and risk level. Glass or brittle plastics not in the production or storage areas shall be included in the register on the basis of risk.

4.1.5.2 Checks shall be conducted on the condition of the items at a specified frequency that is based on the level of risk to the product, these checks shall be **recorded** and maintained.

4.1.5.3 Where unacceptable conditions are identified, these shall be **recorded** and corrective actions conducted in a timely manner.

4.1.6 SHARPS AND METAL CONTROL

4.1.6.1 The organisation shall define the controls for the use of sharp tools, such as knives, blades, needless, and wires to prevent stock item contamination in a **documented procedure** with **records** maintained. This procedure shall cover:
- The issuance and management of sharp tools within manufacturing, storage, and related areas, including engineering workshops and laboratories.
- Keeping **records** of tool replacements or instances of breakage.

4.1.6.2 The use of snap-off blade knives is prohibited.

4.1.7 OTHER CONTROLS

4.1.7.1 Labels and notices attached to equipment shall be designed to be easily cleanable and securely affixed. They shall not pose any risk to product safety, legality, or quality.

4.1.7.2 If wooden equipment such as desks, chairs, and tables present a potential contamination risk, it shall be properly sealed to allow for effective cleaning. All such equipment shall be maintained in a clean condition, kept in good repair, and free from splinters or any other possible sources of physical contamination.

4.1.7.3 The use of staples, paper clips, and drawing pins is prohibited in open product areas. If staples or similar materials are used for packaging or closures, suitable measures shall be implemented to minimize the risk of contamination.

4.1.7.4 Portable handheld devices provided by the site - such as mobile phones, tablets, and measuring instruments—shall be managed and controlled to prevent any risk of physical contamination.

4.2 PERSONNEL RISK ASSESSMENTS

4.2.1 The organisation shall establish and maintain a Personnel **Risk assessment** Program to identify, assess, and control potential risks associated with personnel activities that may impact product safety, legality, and quality. This shall then set the framework for the hygiene programme outlined within section 6.5. This shall be **documented** and reviewed at least annually.

4.2.2 The **risk assessment** process shall evaluate potential hazards related to personnel, including but not limited to:
- Health & Hygiene Risks: Illness, infections, open wounds, or skin conditions that could pose a contamination risk.
- Behavioral Risks: Poor hygiene practices, failure to follow procedures, or unauthorized actions within production areas.
- Physical Contamination Risks: Loose personal items such as jewelry, watches, or personal belongings that could contaminate stock items.
- Zoning Risks: Unauthorized access to high-risk areas or failure to follow cross-contamination control procedures.
- Training Deficiencies: Lack of awareness or failure to follow hygiene and safety protocols

4.2.3 To mitigate identified risks, the organisation shall implement control measures including:
- Hygiene & Medical Screening: Employees shall undergo routine health checks as required
- Personal Protective Equipment (PPE): Mandatory use of designated workwear, gloves, hairnets, and other

PPE as required by **risk assessment**s.
- Access Control: Restricted access to high-risk areas based on training and authorization levels.
- Prohibited Items Policy: Enforcement of restrictions on jewelry, watches, and personal items in processing areas.
- Behavioral Monitoring: leadership shall observe personnel compliance with hygiene and safety procedures.

5.0

GMP SAFETY AND QUALITY MANAGEMENT

(MANAGEMENT ELEMENT)

5.0 GMP SAFETY AND QUALITY MANAGEMENT

5.1 NON-CONFORMANCES

5.1.1 GENERAL

5.1.1.1 The organisation shall define the controls for non-conformances in a **documented procedure** with **Records** maintained.

5.1.1.2 Control of non-conformances shall be applied throughout the GMP management system and cover a range of situations such as non-conforming materials, non-conforming bulk, non-conforming product and general failures in compliance. These shall include the effective identification and management of any affected stock items before a decision has been made on their final disposition.

5.1.1.3 Non-Conforming stock items shall be reviewed periodically, or at least annually, to check for **trends** or recurrence of a particular issue.

5.1.2 NON-CONFORMANCE CONTROLS

5.1.2.1 The organisation shall ensure that non-conforming stock items are clearly identified and effectively managed to prevent unauthorised release.

5.1.2.2 Non-conforming stock items shall be assessed, and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be **documented** and **records** maintained.

5.1.2.3 Decisions to destroy or to reprocess shall be approved by the personnel responsible for Technical Compliance, with support from the customer, where applicable.

5.1.2.4 The method of reprocessing shall be defined and approved. Inspections shall be carried out on the reprocessed stock items. Results shall be reviewed by authorized personnel in order to verify the conformity to the acceptance criteria.

5.1.3 EXTERNALLY SOURCED STOCK ITEMS

5.1.3.1 Where non-conforming stock items are the result of the supplier, an effective communication system shall be in place to notify the supplier of the situation.

5.1.3.2 The supplier shall then conduct an effective root cause analysis with appropriate corrective actions reported back in a timely manner.

5.2 CORRECTIVE AND PREVENTATIVE ACTIONS (CAPA/VA)

5.2.1 The organisation shall define the controls for Corrective and Preventative actions in a **documented procedure** for the purpose of **recording**, handling and correcting issues identified in the stock item safety and GMP management system.

5.2.2 The site procedures shall include the completion of corrective actions, root cause analysis and implementation of preventive action within appropriate timescales.

5.2.3 Where a situation places the safety or legality of a stock item at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including:
- clear documentation of the situation
- the corrective action to address the immediate issue

- appropriate timescales for corrective and preventive actions
- the person(s) responsible for corrective and preventive actions
- verification that the corrective and preventive actions have been implemented and are effective.

NOTE 1 CAPA/VA's can be applied throughout the GMP management system and cover a range of situations such as complaints, non-conforming materials, non-conforming product, recalls, internal audit findings and general failures in compliance.

5.3 CONCESSIONS

5.3.1 GENERAL

5.3.1.1 The organisation shall define the controls for concessions in a **documented procedure** with **records** maintained.

5.3.1.2 Deviations from the specified requirements shall be authorized with sufficient data to support the decision. Authorizations shall not pose a conflict of interest and be approved by a member of Technical Compliance.

NOTE 1 Deviations from planned events are not just associated with stock items but also processes and controls for the GMP management system

5.3.1.3 Corrective action shall be made to prevent the recurrence of the concession, where **trends** are identified or as applicable.

5.3.1.4 Concessions shall be reviewed periodically, or at least annually, to check for **trends** or recurrence of a particular issue with **Records** maintained.

5.4 TRACEABILITY

5.4.1 GENERAL

5.4.1.1 Traceability is fundamental to the effective management of customer complaints and product recalls. To aid this, the organisation shall be able to trace and follow all raw materials through manufacturing (including outsourced operations) to the distribution of the finished product to the customer and from the finished product supplied to the customer through manufacturing, back to the raw materials.

5.4.1.2 The site shall have a **documented procedure** designed to maintain traceability throughout the organisation's operations. At a minimum, this shall include:
- how the traceability system works;
- the stock item identification systems (such as labelling and coding of raw materials, work in progress, finished products), and **Records** required.

5.4.1.3 Identification of raw materials, work in progress, finished products, non-conforming products and quarantined goods shall be adequate to ensure traceability.

5.4.1.4 The traceability process shall be evaluated at least annually, including the accuracy of the procedure and **Records** maintained. The traceability evaluation shall establish both forwards and backwards methods are effective.

NOTE 1 This can be combined with the product recall evaluation.

5.5 COMPLAINTS

5.5.1 GENERAL

5.5.1.1 The organisation shall define the controls for complaints in a **documented procedure** with **records** maintained.

5.5.1.2 All complaints shall be recorded and investigated and the results of the investigation into the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the complaints identified shall be carried out promptly and effectively.

5.5.1.3 In the case of contracted operations, the contract giver and acceptor shall agree on the process for managing complaints.

5.5.1.4 Authorized personnel shall centralise all complaints and their associated data, including:
- initial customer communication;
- reports produced;
- root cause, corrective, preventative and verification actions;
- customer follow-up;
- notification to authorities, where appropriate.

5.5.1.5 Appropriate follow-up on the affected batch(s) shall be completed.

5.5.1.6 Complaint investigations and follow-up shall include:
- steps to correct the defect, where appropriate;
- steps to prevent recurrence of the defect;
- checking other batches in order to determine whether they are also affected, where appropriate.

5.5.1.7 Complaints shall be reviewed periodically, or at least annually, to check for **trends** or recurrence of a particular issue and **records** maintained.

5.6 RECALLS

5.6.1 GENERAL

5.6.1.1 The organisation shall define the controls for product recalls in a **documented procedure** with **records** maintained.

5.6.1.2 When a product recall decision is made, appropriate steps shall be taken to complete the recall, ensuring full traceability and accountability of stock affected and implement corrective actions.

5.6.1.3 In the case of contracted operations, the contract giver and acceptor shall agree on the process for managing recalls. This shall be **documented** within the agreement.

5.6.1.4 The product recall team/authorised personnel shall coordinate the recall process.

5.6.1.5 Product recall operations shall be initiated promptly, carried out in a timely manner, and account for all produced stock.

5.6.1.6 The appropriate authorities shall be notified of recalls which could have an impact upon consumer safety.

5.6.1.7 Recalled products shall be identified and stored separately in a secure area while awaiting a decision.

5.6.1.8 The product recall process shall be evaluated at least annually through a mock simulation with key timings **recorded**, including the accuracy of the procedure and the effective awareness of recall responsibilities for personnel against the procedure.

5.7 PROCUREMENT AND SUBCONTRACTING

5.7.1 SUBCONTRACTING AND OUTSOURCING

5.7.1.1 This clause defines subcontracting as but not limited to:
- manufacturing;
- packaging;
- sorting or reworking.

5.7.1.2 This clause defines outsourcing as, but limited to:
- pest control;
- laundry and cleaning services;
- transport and distribution;
- storage;
- laboratory services;
- calibration services;
- waste management;
- external expertise e.g., consultants, training providers;
- servicing and maintenance of equipment;

5.7.1.3 A written contract or agreement shall be established, mutually confirmed and controlled between the contract giver and the contract acceptor covering subcontracted activities.

5.7.1.4 A **documented** contract or agreement shall be drawn up between the contract giver and the contract acceptor which specifies their respective duties and responsibilities.

5.7.1.5 The organisation shall be able to demonstrate that, where any subcontracting activities are undertaken off-site, this has been declared to the customer and, where required, **documented** approval agreed.

5.7.1.6 The contract giver shall evaluate the contract acceptor's capability and capacity to perform the contracted operations effectively. This assessment shall include verification of the contract acceptor's compliance with applicable guidelines and quality requirements. The contract giver shall also implement appropriate oversight measures, such as inspections and positive release procedures, to ensure that operations are conducted in accordance with the agreed terms.

5.7.1.7 The contract giver shall provide the contract acceptor with all the information required to carry out the operations correctly. These requirements shall be **documented** within the contract, agreement or operation specific **specification**, which includes an effective traceability system. This shall include any specific handling requirements for the stock items.

5.7.1.8 The contract acceptor shall not subcontract any part of the contracted work to a third party without obtaining the prior written approval and consent of the contract giver. In cases where subcontracting is approved, the contract acceptor shall establish formal arrangements with the third party to ensure that all operational information is made fully available to the contract giver, in a manner consistent with the terms and expectations of the original contract.

5.7.2 SUPPLIER APPROVAL

5.7.2.1 The organisation shall conduct supplier approvals or goods in accordance with a **documented procedure** and ensure that **records** are maintained of suppliers, their approval status, and their scope of approval, based upon risk analysis and defined performance criteria in an approved supplier register.

5.7.2.2 The procedure for initially approving manufacturing sites that produce raw materials impacting product safety, legality, and quality shall be risk-based. Approval may be granted through one or a combination of

the following methods, with every approach taken reviewed and approved by a competent individual:
- A valid certification of a product safety management system, such as certification to an applicable ISO or BRC Global Standards. The certification scope shall cover the stock items being purchased
- Certification to a quality management system that includes an evaluation of traceability and confirmation that supplied products are safe and compliant, such as a declaration of compliance.
- Supplier audits that assess the quality management system, traceability, and prerequisite controls, conducted by an experienced and competent individual. A complete audit report shall be maintained.
- A supplier approval questionnaire (SAQ) or supplier-provided documentation may be used for approval if a valid risk-based justification is **documented**. The questionnaire shall cover the supplier's product safety system, verification of traceability, and prerequisite controls

5.7.2.3 If approval cannot be established using the above criteria, the organisation shall define and justify its alternative approval and evaluation process to ensure that all supplied stock items meet safety, legality, and quality requirements and comply with specified standards.

5.7.2.4 The organisation shall define the controls for the approval and monitoring of suppliers of services covering subcontracting and outsourcing in a **documented procedure** with **records** maintained.

5.7.2.5 The frequency of approval and monitoring shall be **risk-based** or whenever significant changes occur and consider:
- risk to the safety and quality of products
- compliance with any specific legal requirements
- potential risks to the security of the product (i.e. risks identified in the vulnerability and product defense assessments).

5.7.3 PURCHASING

5.7.3.1 The organisation shall define the controls for the purchasing of goods and services in a **documented procedure**.

5.7.3.2 Purchases shall only be made from suppliers and service providers who have been assessed and approved.

5.7.3.3 The organisation shall issue a purchase order to approved suppliers for the required goods or services, ensuring that it includes, at a minimum:
- a description of the requested goods or services.
- a quantity of the requested goods or services
- any necessary delivery timelines specified by the organisation
- relevant organisational requirements related to the goods or services

5.7.3.4 The organisation shall maintain **records** of all purchases, including purchase orders.

5.8 CHANGE CONTROL

5.8.1 Changes that could affect the quality of stock items should be assessed and approved by authorized personnel on the basis of sufficient data.

5.9 INTERNAL AUDITS

5.9.1 GENERAL

5.9.1.1 The organisation shall define the controls for internal audits in a **documented procedure** which shall include:
- the frequency of the internal audits, at minimum annually
- the scope of the internal audits
- **records** to be completed
- the internal auditors assigned to each audit.
- the senior management acknowledgement of each internal audits outcome.
- the method of recording and managing any non-conformities identified

5.9.1.2 The organisation shall conduct internal system audits against the clauses of this standard, as per a defined programme or schedule, to ensure the GMP management system:
- conforms to the organisation's requirements and procedures
- conforms to the requirements of this Standard
- is effectively implemented and maintained.

5.9.1.3 Internal audits shall be conducted by specially designated personnel with demonstrated competence or under supervision of such personnel. Auditors shall perform assessments independently and thoroughly, either on a scheduled basis or as needed. Competency shall be evidenced through **documented** training and the quality of audit reports.

5.9.1.4 All findings (positive and negative) identified during the internal audit shall be evaluated and shared with appropriate management and recorded on the report, including:
- objective evidence
- evidence of conformity;
- evidence of actual nonconformities and their risk level
- evidence of potential nonconformities and/or
- opportunities for improvement made by the internal auditors.

5.9.1.5 Internal audit follow-up shall confirm the satisfactory completion or implementation of corrective action.

5.9.1.6 The internal audit programme shall be fully implemented.

6.0

PERSONNEL

(MANAGEMENT ELEMENT)

6.0 PERSONNEL

6.1 GENERAL

6.1.1 The organisation shall **document** who it considers "Senior Management" and, thus, who is responsible for the requirements of Senior Management called out by this Standard. The organisation shall ensure that "Senior Management" includes the senior-most manager(s) responsible for the organisation.
NOTE 1 Reference clause 6.2.1.3.

6.1.2 The implementation of Good Manufacturing Practices shall be the responsibility of Senior Management and shall require the participation and commitment of personnel in all departments and at all levels within the company. Senior Management shall evidence this commitment by developing, **documenting** and publishing a GMP policy that:
- summaries the organisation's culture of GMP;
- is easily understood; and
- be communicated and easily understood by all personnel.

6.1.3 The organisation shall be supported by the Senior Management of the company.

6.1.4 Management shall define and communicate the areas in which authorized personnel are allowed to access.

6.2 RESPONSIBILITIES OF PERSONNEL

6.2.1 All personnel shall:
- know their position in the organisational structure;
- know their defined responsibilities and activities;
- have access to and comply with documents relevant to their particular responsibility scope;
- comply with personal hygiene requirements;
- be encouraged to report irregularities or other non-conformities which may occur at the level of their responsibilities;
- have adequate education training and skills to perform the assigned responsibilities and activities.

6.2.2 Senior Management shall ensure that responsibilities and authorities, relative to the GMP management system, are **documented** and authorities include:
- a clear statement of the GMP management system's importance and each individual's specific responsibilities to it;
- who is responsible for implementing procedures; and
- who will act as point of contact for third parties when representing the GMP management system.
NOTE 1: Identifying responsible persons by title is sufficient.
NOTE 2: Responsibilities and authorities may be documented within job descriptions and/or procedures.

6.2.3 Senior Management shall ensure that personnel have the necessary authority to carry out their responsibilities.

6.3 ORGANISATION

6.3.1 The organisation shall define the personnel structure in an organisation chart in a **documented** organogram with each Technical Compliance department shown as independent from production.

6.3.2 There shall be clearly assigned and **documented** deputies for all key roles.

6.3.3 The organisation shall ensure that adequate staffing levels are maintained across various operational areas including any employees, contractors, temporary help, etc., necessary for the effective implementation of the

management system processes, and/or to ensure quality of products and services. It shall be appropriate for the size of the company and the diversity of its products.

6.4 COMPETENCE & TRAINING

6.4.1 The organisation shall define the controls for its training programme in a **documented procedure.**

6.4.2 The training needs of all personnel, regardless of position in the organisation, shall be identified in a training programme with **records** maintained. The organisation shall ensure that **records** of training are maintained from all sources (internal and external). These shall include:
- the name of the trainee and confirmation of attendance. Either physically signed or digitally signed
- the date and duration of the training
- the title, procedure or course contents, as appropriate
- the training provider (external or internal provider).
- The details of the competency assessment/evaluation carried out and level of achievement.

6.4.3 Training shall be regarded as a constant and on-going process that is subject to regular updates with **records** maintained.

6.4.4 All personnel, including temporary workers and contractors, where applicable, shall receive proper training before starting work and be adequately supervised.

6.4.5 Inductions shall be conducted for all personnel which shall include the company hygiene rules, the GMP policy, their responsibilities and organisation specific awareness.

6.4.6 GMP awareness training shall be provided to all personnel and refreshed at least annually.

6.4.7 The organisation shall provide additional training as required (e.g., on-the-job training, skills advancement, process improvement training, etc.) to ensure quality.

6.5 PERSONNEL HYGIENE AND HEALTH

6.5.1 PERSONNEL HYGIENE

6.5.1.1 Hygiene programmes shall be established and adapted to the needs of the organisation. These requirements shall be understood and followed by every person whose activities take them into GMP Control Zones. The organisation shall maintain a **documented procedure** defining its hygiene program and supported by the **documented** personnel **risk assessments** program.

6.5.1.2 Suitably located and sufficient hand-washing facilities shall be available and shall be uses regularly, including before starting work, after breaks, after using the toilets, after smoking or any other unhygienic activity. Hand sanitizer may be used to sanitize but shall not be used as a substitute for hand washing. Hand-washing facilities shall provide, as a minimum:
- sufficient quantity of water at a suitable temperature to encourage handwashing
- suitable hand-drying facilities
- suitable signs for prompt use

6.5.1.3 Every person entering GMP Control Zones shall wear appropriate clothing and protective garments to avoid contamination of stock items, as established by the hygiene program and **risk assessments**, which are not stored in locations which come into contact with personal clothing.

6.5.1.4 Eating (including the eating of confectionery and chewing of gum), drinking and smoking shall not be allowed in the GMP control zone, including the storage of these items, with the exception of water drinking stations so long as they are not near stock items, determined on the basis of a **risk assessment**.

6.5.1.5 Personal medication in the GMP Control Zones shall be avoided where possible or controlled through a **risk assessment** on a case-by-case basis.

6.5.1.6 Any unhygienic practice within the GMP Control Zones or in any other area where the stock items might be adversely affected shall be forbidden, as established by the hygiene program.

6.5.2 PERSONNEL HEALTH

6.5.2.1 Steps shall be taken to ensure, as far as is practicable, that any person affected by an apparent illness or having open lesions on the exposed body surface shall be excluded from direct contact with stock items until the condition is corrected or determined by medical personnel that the quality of stock items will not be compromised.

6.6 VISITORS, CONTRACTORS AND UNTRAINED PERSONNEL

6.6.1 Visitors or untrained personnel shall preferably not be taken into GMP Control Zones. If this is unavoidable, they shall be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They shall be closely supervised.

6.6.2 A system for evaluating the health status of visitors and contractors shall be established and assessed before granting them access to the site. **records** of this assessment shall be maintained.

NOTE 1: This can be in the form of a visitor questionnaire.

7.0
PERMISES AND SITE STANDARDS
(OPERATIONAL ELEMENT)

7.0 PREMISES & SITE STANDARDS

7.1 GENERAL

7.1.1 Premises shall be located, designed, constructed and utilized so as:
- to ensure protection of the stock items;
- to permit efficient cleaning, if necessary, sanitizing and maintenance;
- to minimize the risk of mix-up of stock items.

7.1.2 Premises design recommendations are described in these guidelines. Design decisions shall be based on the type of cosmetic product produced, existing conditions, cleaning and, if necessary, sanitizing measures used.

7.1.3 The organisation shall have a **documented** site plan in place.

7.2 CONTROL ZONES

7.2.1 GMP control zones and their risk status shall be clearly defined and **documented** on the site plan**.**

7.2.2 Separate or defined areas shall be provided for storage, production, quality control, ancillary, washing and toilets.

7.2.3 Clear signage shall be provided to ensure accurate information is provided to personnel entering the GMP control zones, so they understand the restrictions and controls in place.

7.3 FLOW

7.3.1 The flow of stock items, personnel and waste throughout the premises shall be clearly defined to prevent any mix-ups and **documented** on the site plan. The layout from intake to dispatch shall be organized to minimize the risk of contamination or damage to stock items.

7.3.2 Sufficient space shall be provided to ensure enough space for receipt, storage, and production and prevent mix-ups. Premises shall have adequate working space and storage capacity for safe and hygienic operations.

7.4 INFRASTRUCTURE

7.4.1 Design considerations shall be given to the following:
- Walls, floors, ceilings, doors and windows
- exposed overhead roof beams, pipes and ducts are to be avoided, where possible, on the basis on risk.
- exposed pipes shall not touch walls, but be suspended from or supported by brackets, sufficiently separated to allow thorough cleaning
- alternatively, specific measures shall be taken to protect the stock items.

7.4.2 The floors, walls, ceilings, and windows in GMP control zones shall be designed or constructed for ease of cleaning and, if necessary, sanitization, to prevent the risk of stock items contamination. They shall be maintained in good repair and facilitate effective cleaning.

7.4.3 Windows shall be protected, and regularly checked for breakages, and **records** maintained. If windows are opened to the outside environment, they shall be properly screened. Regular checks shall be carried out in accordance with a **risk assessment**.

7.4.4 Floors shall be suitably hard-wearing to meet the demands of the operations and withstand cleaning materials and methods. There shall be no damaged, delaminating or flakey painted floors.

7.4.5 Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.

7.4.6 Suitable and sufficient ventilation to prevent condensation, excessive dust, heat and fumes, where applicable, shall be provided, and regularly maintained.

7.4.7 Pipework, drains, guttering, and ducts shall be installed and maintained in a manner that prevents drips, leaks, or condensation from contaminating stock items, surfaces, or equipment. These systems shall be subject to regular maintenance to ensure continued compliance with hygiene and contamination control standards.

7.4.8 Both internal and external drains shall be kept clear and clean and shall not allow back flow.

7.4.9 Pooling water shall be avoided. Where pooling of water exists, there shall be sufficiently **recorded** actions in place to rectify in a timely manner.

7.5 STAFF FACILITIES (BREAK ROOMS, LOCKER ROOMS, CHANGING ROOMS, WASHING ROOMS AND TOILETS)

7.5.1 The organization shall provide suitable and clean staff facilities for all personnel. These facilities shall be clearly separated from production and storage areas to maintain hygiene and operational integrity. Where necessary, adequate showering and changing facilities shall also be provided to support personal hygiene requirements.

7.5.2 Personal belongings shall be stored in suitable locations away from product, storage and eating areas and not come into contact with GMP required PPE.

7.5.3 Where food is provided, either by vending machines or catering facilities, they shall not present a health risk to personnel.

7.5.4 Where cleaning activities are undertaken within the staff facilities, these shall have their own dedicated cleaning equipment, separate from GMP Control Zones.

NOTE 1: This can be in the form of colour coded equipment.

7.6 CLEANING AND SANITIZATION

7.6.1 The organisation shall define the controls for its cleaning and sanitization programme/schedule in a **documented procedure**, specific to each GMP control zone, staff facilities and office spaces. These shall include:
- Cleaning equipment required to conduct the activity
- Cleaning Materials required and their dilutions from the AMR (“Approved Materials Register”)
- Contact times, as required.

7.6.2 The site shall be maintained in a clean condition with all cleaning activities, specifically the GMP Control Zones, **recorded**, and not pose a risk to stock items or personnel

7.6.3 All cleaning and sanitizing activities shall be validated, taking into account the materials used to ensure they are effective at the specified dilutions and contact times.

7.6.4 All cleaning equipment used, shall be kept clean and in a good state of repair.

NOTE 1 – Cleaning and sanitization is referenced within the standard for both the site premises and equipment used to produce stock items – see 7.5. A single approach programme for both site and equipment would be accepted.

7.7 MAINTENANCE

7.7.1 Premises used in activities described in these guidelines shall be maintained in a good state of repair through a **documented** preventative maintenance programme and **records** of activities maintained

7.7.2 The organisation shall maintain a signed, **documented** contract with the subcontractor defining how it manages maintenance activities, where applicable.

7.8 CONSUMABLES

7.8.1 Consumables used for premises shall not affect the quality of the stock items.

7.9 PEST CONTROL

7.9.1 The organisation shall maintain a signed, **documented** pest control agreement and programme, appropriate for the premises, with **records** maintained and signed/acknowledged by both the service provider and the person responsible within the organisation

7.9.2 Premises shall be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin.

7.9.3 Measures shall be taken to control the exterior of the premises to prevent attracting or harbouring pests.

7.9.4 Where corrective actions are specified by the pest control provider, these shall be actioned in accordance with the providers timeframe and **records** maintained.

7.9.5 Pest control activity shall be carried out in accordance with local laws and legislation.

7.10 WASTE

7.10.1 Wastes shall be disposed of in a timely and sanitary manner and not pose a **risk** to the stock items.

7.10.2 Using findings from production and quality control laboratories, the company shall define the different types of waste that could affect the quality of the stock items.

7.10.3 The flow of waste shall not impact on the production and laboratory operations.

7.10.4 Appropriate measures shall be taken concerning collection, transportation, storage and disposal of waste.

7.10.5 Containers of waste shall be properly closed and identified as to contents and other information, as appropriate.

7.10.6 Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and **records** of removal shall be maintained and available for audit.

8.0

EQUIPMENT

(OPERATIONAL ELEMENT)

8.0 EQUIPMENT

8.1 GENERAL

8.1.1 Equipment shall be suitable for the intended purpose and capable of being cleaned and, if necessary, sanitized and maintained. If automated systems are introduced such as CIP, they shall be taken into account.

8.1.2 Major equipment shall be readily identifiable and defined.

8.2 EQUIPMENT DESIGN AND PLACEMENT

8.2.1 Operational equipment shall be designed to prevent contamination of the stock items.

8.2.2 Bulk product containers, such as IBCs and barrels, shall be protected from air contaminants, such as dust and moisture.

8.2.3 Transfer hoses and accessories that are not in use shall be cleaned and, if necessary, sanitized, kept sealed and protected from dust, splash or other contamination.

8.2.4 The materials used in the construction and use of equipment shall be compatible with stock items and the cleaning and sanitizing agents such as oils, lubricants and greases.

8.2.5 Equipment shall be located so that movement of stock items, mobile equipment and personnel does not pose a **risk** to quality.

8.2.6 Reasonable access under, inside and around equipment shall be provided for maintenance and cleaning.

8.3 NEW EQUIPMENT ACCEPTANCE

8.3.1 The design and the installation of new equipment shall be conducted to ensure suitability to the GMP management system, with **risk**s, procedures, cleaning, maintenance and practices created/updated where appropriate, and **records** maintained.

NOTE 1 This is sometimes referred to as factory acceptance testing (FAT) or equipment verification and validation

8.4 CALIBRATION

8.4.1 The organisation shall define the controls for calibration in a **documented procedure**.

8.4.2 The site shall identify, and control in-line and off-line measuring equipment used to monitor critical control measures, where applicable, and product safety, legality and quality. This shall include, as a minimum:
- a register of equipment and its location
- an identification code and re-calibration due date, where applicable
- the calibration date, as applicable, and any adjustments required
- prevention from adjustment by unauthorised personnel
- protection from damage, deterioration and misuse.

8.4.3 The accuracy of measuring equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.

8.4.4 All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on **risk** and **records** maintained. This shall be carried out by trained personnel to a defined method, to ensure accuracy within defined parameters. All results shall be recorded.

8.4.5 If results of calibration are out-of-acceptance criteria, measuring instruments shall be appropriately identified and removed from service. An out-of-calibration condition shall be investigated to determine if there is any impact to the quality of the stock items and appropriate steps taken based on this investigation.

8.5 CLEANING AND SANITIZATION

8.5.1 The organisation shall define the controls for its cleaning and sanitization programme in a **documented procedure**, specific to each piece of equipment. These shall include:
- Cleaning equipment required to conduct the activity
- Cleaning materials required and their dilutions from the AMR ("Approved Materials Register")
- Contact times, as required.

8.5.2 All equipment shall be maintained in a clean condition with all cleaning activities **recorded**, and not pose a risk to stock items or personnel.

8.5.3 All cleaning and sanitizing activities shall be validated, taking into account the materials used to ensure they are effective at the specified dilutions and contact times.

8.5.4 All cleaning equipment used, shall be kept clean and in a good state of repair.

NOTE 1 – Cleaning and sanitization is referenced within the standard for both the site premises and equipment used to produce stock items – see 6.6. A single approach programme for both site and equipment would be accepted.

8.6 MAINTENANCE

8.6.1 The organisation shall maintain a signed, **documented** contract/agreement with the subcontractor defining how it manages maintenance activities, where applicable.

8.6.2 Equipment used shall be maintained in a good state of repair through a **documented** preventative maintenance programme and **records** of activities maintained

8.6.3 Defective equipment shall be identified accordingly, excluded from use and isolated if possible.

8.6.4 Maintenance operations shall not affect the quality of stock items.

8.7 CONSUMABLES

8.7.1 Consumables used for equipment shall not affect the quality of stock items.

8.8 AUTHORIZATIONS AND ACCESS

8.8.1 Equipment or automated systems used in production and control shall be accessed and used by authorized personnel.

8.8.2 Where passwords are used to gain access to equipment systems, these shall be protected so as to not allow unauthorised access.

9.0
PURCHASING AND GOODS INTAKE
(OPERATIONAL ELEMENT)

9.0 PURCHASING AND GOODS INTAKE

9.1 GENERAL

9.1.1 The organisation shall ensure that verification of received items and services is performed in accordance with a **documented procedure**.

9.1.2 The organisation shall ensure that purchased stock items are verified as conforming to requirements before use through the use of a **specification** outlining the requirement and acceptance criteria.

9.2 GOODS INTAKE

9.2.1 The purchase order, the delivery note, and the delivered materials shall match.

9.2.2 The integrity and acceptance criteria of the stock items shall be compared to the specification before release. If necessary, additional checks of transport shall be performed.

9.2.3 Raw materials and packaging materials showing defects that might affect finished product quality shall be held pending a decision.

9.2.4 Raw materials and packaging materials shall be identified in an appropriate way according to their status such as hold pending release, released, quarantined pending investigation of an issue or rejected. Other systems can replace this physical system of identification, if they ensure the same level of assurance.

9.3 TRACEABILITY IDENTIFICATION

9.3.1 Containers of raw materials and packaging materials shall be labelled in order to identify the material and the batch information.

9.4 RELEASE

9.4.1 There shall be a **documented** system in place to ensure that only released stock items are used.

9.4.2 The release of materials shall be carried out by the authorized personnel responsible for Technical Compliance or their deputy.

9.5 WATER USED AS A STOCK ITEM

9.5.1 Where water is produced on site through a treatment system, **documented** controls shall be in place to support the production of potable water at the defined quality level either testing or monitoring of process parameters. **Records** shall be maintained along with acceptance criteria.

9.5.2 Where water is produced on site through a treatment system, Water treatment equipment shall be set up so as to avoid stagnation and risks of contamination and shall permit sanitization.

9.5.3 Where water is produced on site through a treatment system, materials used in water treatment equipment shall be selected to ensure that water quality is not affected.

9.5.4 Where water is purchased as a raw material, the raw material purchasing requirements outlined in the document are applicable.

10.0
PRODUCTION
(OPERATIONAL ELEMENT)

10.0 PRODUCTION

10.1 GENERAL

10.1.1 The organisation shall define the controls for the manufacture of bulk products, production of filled product and production of packed product in a **documented procedure**.

10.1.2 At each stage of manufacturing operations and packaging operations, measures shall be taken to produce a finished product that meets the defined acceptance criteria.

10.2 BULK MANUFACTURING OPERATIONS

10.2.1 ESSENTIAL DOCUMENTATION AVAILABILITY

10.2.1.1 Relevant documentation shall be available at each stage of manufacturing operations.

10.2.1.2 Manufacturing operations shall be carried out according to manufacturing **documentation**, including:
- suitable equipment, which is recorded on works orders for traceability
- formula for the bulk product
- list of all raw materials identified according to relevant documents indicating traceability codes/batch numbers and quantities required
- detailed method of manufacture and **specification** for each stage, such as addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning and, if necessary, sanitizing of equipment, and bulk product transfer.

10.2.2 PRE-START CLEARANCE CHECKS

10.2.2.1 Before starting any bulk manufacturing operations, it shall be ensured that **records** are maintained of the following:
- all documentation relevant to the manufacturing operations is available
- all raw materials are available, within their re-evaluation period and released
- suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized
- The area is clear of non-specified materials to avoid mixing with materials from the previous operation.

10.2.3 TRACEABILITY IDENTIFICATION

10.2.3.1 A traceability code shall be assigned to each batch of manufactured bulk product.

NOTE 1 This number does not need to be identical with the batch number that appears on the label of the finished product, but, if not, it shall be easy to relate to that number.

10.2.4 IDENTIFICATION OF IN-PROCESS OPERATIONS

10.2.4.1 In accordance with the formula, all raw materials shall be measured or weighed into clean and suitable containers labelled with appropriate identification or directly into the equipment used for manufacturing. Where the exact quantity of material required cannot be achieved, tolerances shall de defined.

10.2.4.2 At all times, it shall be possible to identify major equipment, containers of raw materials and containers of bulk products.

10.2.4.3 Identification of containers of bulk products shall indicate:
- name or identifying code
- traceability code

- storage conditions when such information is critical to assure the quality of the stock item.

10.2.5 **IN-PROCESS CONTROL**

10.2.5.1 In-process controls and their acceptance criteria shall be defined in a **specification**.

10.2.5.2 In-process controls shall be performed according to a defined programme, at the defined frequencies.

10.2.5.3 Any result outside the acceptance criteria shall be reported and appropriately investigated.

10.2.6 **RE-STOCKING**

10.2.6.1 If raw materials remain unused after weighing and are intended and deemed acceptable to return to stock, their containers shall be closed and properly identified.

10.3 **FILLING & PACKAGING OPERATIONS**

10.3.1 **ESSENTIAL DOCUMENTATION AVAILABILITY**

10.3.1.1 Relevant **documentation** shall be available at each stage of packaging operations.

10.3.1.2 Packaging operations shall be carried out according to packaging **documentation** including:
- suitable equipment, which is recorded on works orders for traceability, as required
- list of packaging materials defined for the intended finished product
- detailed packaging **specification** such as filling, closing, labelling, and coding.

10.3.2 **PRE-START CLEARANCE CHECKS**

10.3.2.1 Before starting any filling and/or packaging operations, it shall be ensured that **records** are maintained of the following:
- all documentation relevant to the filling/packaging operations is available
- all bulk and packaging materials are available, within their re-evaluation period and released
- specified and suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized
- The area is clear of non-specified materials and equipment to avoid mixing with materials from the previous operation.
- any coding to permit identification of the stock item is defined.

10.3.3 **TRACEABILITY IDENTIFICATION**

10.3.3.1 A traceability code shall be assigned to each unit of finished product to allow for traceability to production **records**.

Note 1 This number does not need to be identical with the batch number that appears on the label of the bulk product, but, if not, it shall be easy to relate to that number.

10.3.4 **PACKAGING LINE IDENTIFICATION**

10.3.4.1 At all times, it shall be possible to identify the packaging line with its name or identifying code, the name or identifying code of the finished product and the traceability code

10.3.4.2 Checks of on-line control equipment If used, on-line control equipment shall be regularly checked according to a defined programme and **records** maintained.

10.3.5 **IN-PROCESS CONTROL**

10.3.5.1 In-process controls and their acceptance criteria shall be defined in a **specification**

10.3.5.2 In-process controls shall be performed according to a defined programme, at the defined frequencies.

10.3.5.3 Any result that is outside the acceptance criteria shall be reported and appropriately investigated.

10.3.6 RE-STOCKING

10.3.6.1 If packaging materials remain unused after the filling & packaging operations and are intended and deemed acceptable to return to stock, their containers shall be closed and properly identified.

10.3.7 IDENTIFICATION AND HANDLING OF WORK-IN-PROCESS

10.3.7.1 Filling and labelling are usually a continuous process. Where this is not the case, special measures including segregation and identification shall be applied so that no mix-ups or mislabeling can occur.

10.3.7.2 Packaging lines shall be sufficiently clear from other packaging lines so as to not void the line clearance activity or cause a **risk** to the stock item.

11.0

STORAGE AND DESPATCH

(OPERATIONAL ELEMENT)

11.0 STORAGE AND DESPATCH

11.1 GENERAL

11.1.1 The organisation shall define the controls for stock item storage, release, dispatch and returns in a **documented procedure**(s).

11.1.2 Finished products shall meet the defined acceptance criteria.

11.1.3 Storage, shipment and returns shall be managed in a manner so as to maintain the quality of the stock item.

11.2 STOCK ITEM STORAGE

11.2.1 All stock items, including bulk and finished products, shall be stored under conditions appropriate to their nature to maintain quality and safety.

11.2.2 The maximum storage duration (shelf life) for raw materials, packaging materials, bulk and finished products shall be defined and documented, where appropriate. This may be through **documented procedures**, digital systems, or other verifiable means.

11.2.3 Where applicable, stored products shall be monitored to ensure conditions remain appropriate throughout the storage period.

11.2.4 Stock items shall be stored and handled in a manner appropriate to their specific characteristics, associated risks (e.g., allergens, COSHH requirements), and any declared claims (e.g., organic, vegan).

11.2.5 Storage containers of stock items shall be closed/sealed.

11.2.6 Storage containers for purchased stock items, particularly those made of cardboard or other easily damaged materials, shall be stored off the floor to prevent contamination or deterioration.

11.2.7 When stock items are quarantined or rejected, they shall be stored in their respective physical locations or by using any other system providing the same level of assurance.

11.2.8 Identification of stock item containers shall indicate:
- name and/or identifying code
- traceability code
- storage conditions when such information is critical to assure the quality of the stock item;
- quantity and unit of measure, where required
- Dates, where required.

Where using a digital system for inventory control that produces a barcode identification label, this shall be linked to the systems intake **records** that show the above information.

11.2.9 Measures shall be set up to ensure stock turnover. Except in special circumstances, stock rotation shall ensure that the earliest expiring material is used first (FEFO).

11.2.10 Periodic inventory checks shall be performed to:
- ensure inventory accuracy;
- ensure that acceptance criteria are met.

Any significant discrepancy shall be investigated.

11.3 RE-EVALUATIONS & SHELF LIFE

11.3.1 The organisation shall define the controls for shelf life/expirations of stock items and their re-evaluation activities in a **documented procedure**.

11.3.2 A system shall be set up to re-evaluate materials as appropriate to determine their suitability for use, after a defined period of storage and **records** maintained. The system shall be set up so as to prevent the use of materials which have expired.

11.4 POSITIVE RELEASE

11.4.1 All finished products shall be subject to control and verification using established test methods prior to being released to the market. Each product shall meet defined acceptance criteria to ensure quality, safety, and regulatory compliance.

11.4.2 The release of Work-In-Progress (WIP) and finished products shall be performed exclusively by authorized Technical Compliance personnel or their designated deputies.

NOTE 1 - This ensures that product release decisions are made by individuals with appropriate authority and competence to verify compliance with all quality requirements.

11.5 DESPATCH & SHIPMENT

11.5.1 Measures shall be taken to ensure the shipment of the defined finished product. These shall include, but be limited to:
- Availability of relevant documentation
- Vehicle inspections prior to loading.

11.5.2 Precautions shall be taken to maintain the finished product quality, when appropriate.

11.6 RETURNS

11.6.1 Returns shall be identified in an appropriate way and stored in defined areas.

11.6.2 Returns shall be evaluated against established criteria to determine their disposition upon arrival back to site and release only be given after reevaluation, before placing returns on the market again and avoiding the inadvertent redistribution of unreleased finished product.

12.0
INSPECTIONS AND ACCEPTANCE
(OPERATIONAL ELEMENT)

12.0 INSPECTIONS AND ACCEPTANCE

12.1 GENERAL

12.1.1 Controls are carried out to ensure stock items meet quality criteria, at each stage of operation, before they are released for use or shipment.

12.2 TEST METHODS

12.2.1 The inspection activities shall use established test methods necessary to confirm that the stock item complies with acceptance criteria.

12.2.2 Test methods shall be **documented** to aid in training consistency of application/results and validation.

12.3 ACCEPTANCE CRITERIA

12.3.1 Acceptance criteria, or parameter limits, shall be specified for stock items

12.3.2 All results shall be **recorded** and reviewed. After this review, a decision shall be made on the deposition such as approved – within acceptance criteria, rejected – not within criteria and unusable, quarantined – not within acceptance criteria but potentially acceptable, pending or disposed of.

12.3.3 Out-of-acceptance results shall be reviewed by authorized personnel, such as Technical Compliance, development or customer, and properly investigated. There shall be sufficient **recorded** re-testing results if any additions are performed.

12.3.4 After the investigation, a decision by authorized personnel shall be made, notably in terms of approved, concessioned, rejected, disposed of or pending.

12.4 ANALYTICAL MATERIALS (REAGENTS, SOLUTIONS, REFERENCE STANDARDS, CULTURE MEDIA)

12.4.1 Analytical materials used such as reagents, solutions, reference standards, culture media, etc. shall be identified by the following information:
- the name;
- its strength or concentration, when appropriate;
- expiration date, when appropriate;
- the name and/or initials of the person who prepared it, when appropriate;
- opening date;
- storage conditions, when appropriate.

12.4.2 Where analytical materials are prepared on site, they shall be prepared in accordance with **documented procedure**s and supported through training **records.**

12.5 SAMPLING

12.5.1 Sampling must be conducted by authorized personnel only.

12.5.2 The sampling process shall be clearly defined, including the following elements:
- The sampling method to be used
- The equipment required for sampling

- The designated location and the quantity to be sampled
- Precautions to prevent contamination or deterioration during sampling
- Precautions to prevent contamination or deterioration during sampling
- The method for identifying the sample
- The frequency of sampling

12.5.3 Samples must be identifiable to prevent mix-ups. This can be achieved through:
- A name or unique identifying code
- A traceability code, where applicable
- The date of sampling, if relevant
- The container from which the sample was taken, where applicable
- The specific sampling point, if applicable.

12.6 RETAIN SAMPLE

12.6.1 Where appropriate, or as a customer requirement, identifiable and traceable samples of finished product shall be retained, for a defined period, under the recommended storage conditions and in defined areas.

12.6.2 Identifiable and traceable samples of bulk products shall be retained, for a defined period, in appropriate containers, under the recommended storage conditions and in defined areas.

12.6.3 Sample size of stock items shall allow analyses to be carried out in accordance with local regulations.

13.0
DESIGN AND DEVELOPMENT
(MANAGEMENT ELEMENT)

13.0 DESIGN AND DEVELOPMENT

13.1 DESIGN AND DEVELOPMENT

13.1.1 GENERAL

13.1.1.1 The organisation shall define the controls for product design and development in a **documented procedure**.

13.1.1.2 All finished products shall follow the controlled procedure to ensure compliance with regulatory and quality requirements.

13.1.2 BRIEF

13.1.2.1 The organisation shall define the specific requirements for each product design within a brief that **records** at a minimum the region of intended sale, applicable legislation, inputs (customer needs), controls, verification methods, and outputs to ensure compliance with legal and safety standards.

13.1.3 RAW MATERIALS

13.1.3.1 Raw materials used in cosmetic formulations shall be assessed for suitability, legal compliance, and fraud vulnerability. Technical documentation shall be retained to evidence these assessments. The following aspects shall be verified, where applicable:
- **Compositional Compliance**: Ensure the formulation adheres to specific compositional legislation.
- **Additive Regulations**: Confirm that all additives are permitted and within the maximum usage levels outlined in food supplement additive regulations.
- **Compounded Ingredients**: Verify that all components of compounded ingredients are permitted.
- **Market-Specific Prohibitions**: Ensure that ingredients prohibited in target markets are not present, especially botanical ingredients.
- **Active Ingredient Limits**: Confirm that micronutrient levels comply with regulations in the intended market.
- **Irradiation Status**: Assess the irradiated status of ingredients, particularly botanicals.
- **Genetically Modified (GM) Status**: Confirm that any GM ingredient or GM source is authorized for use in the EU.
- **Patent Compliance**: Verify that the composition does not infringe on existing patents.

13.1.4 RECIPE

13.1.4.1 The organisation shall document detailed formulation **records**, including all raw materials, concentrations, and any changes made throughout development.

13.1.4.2 Any modifications to the recipe shall be recorded with justifications to ensure traceability and compliance with legal and safety requirements.

13.1.5 METHODOLOGY

13.1.5.1 The organisation shall establish **documented** methods of manufacture for each formulation to ensure consistent batch production. These methods shall include specific instructions on raw material additions, mixing times, processing temperatures, and the equipment required.

13.1.5.2 The organisation shall document all process parameters and controls to provide personnel with clear **records** to follow, ensuring reproducibility and compliance with quality and regulatory requirements.

13.1.6 **STABILITY**

13.1.6.1 The organisation shall conduct stability testing to ensure product integrity over its intended shelf life.

13.1.6.2 Stability test results shall be **documented** and reviewed periodically to confirm product compliance.

13.1.7 **COMPATIBILITY**

13.1.7.1 The organisation shall perform compatibility testing between ingredients and packaging materials to ensure no adverse reactions occur.

13.1.7.2 Any findings shall be recorded, and corrective actions shall be taken as necessary to maintain product stability and safety.

13.1.8 **PRESERVATION**

13.1.8.1 The organisation shall verify the efficacy of preservatives through microbiological testing and ensure compliance with regulatory limits.

13.1.8.2 Preservation methods shall be validated and **documented** to confirm their effectiveness in preventing contamination. The critical controls around preservatives shall be included in the method of manufacture to ensure they are properly controlled and consistently applied in each batch.

13.1.9 **RELEASE**

13.1.9.1 The organisation shall ensure compliance with EU Regulation (E- No 1223/2009 by obtaining a Cosmetic Product Safety Report (CPSR) before market release.

13.1.9.2 A qualified safety assessor shall perform a comprehensive safety assessment, and documentation shall be maintained as evidence of compliance.

13.1.9.3 The organisation shall register the product with the applicable authority, such as the Cosmetic Product Notification Portal (CPNP), and comply with national registration requirements in the intended market of sale.

13.1.9.4 All required documentation shall be submitted and maintained to ensure regulatory adherence.

13.1.9.5 The organisation shall establish a final approval process to verify compliance with all regulatory standards before market release.

13.1.9.6 Approval **records** shall be maintained as part of the product documentation.

13.2 **LABELLING**

13.2.1 **INGREDIENT LISTINGS AND ALLERGENS**

13.2.1.1 The organisation shall ensure full ingredient disclosure using the INCI nomenclature as per legal requirements.

13.2.1.2 Allergenic substances shall be clearly highlighted in accordance with applicable regulations.

13.2.2 **RESPONSIBLE PERSON**

13.2.2.1 The organisation shall designate a legally responsible person to oversee compliance with cosmetic regulations.

13.2.2.2 The responsible person's contact details shall be clearly stated on the product label.

13.2.3 BATCH CODE/NUMBER

13.2.3.1 The organisation shall implement a unique batch coding system for each product to ensure full traceability.

13.2.3.2 Batch **records** shall be maintained for quality control and recall purposes.

13.2.4 SHELF LIFE

13.2.4.1 The organisation shall conduct stability testing to determine the appropriate shelf life of each product.

13.2.4.2 Where applicable, a "Period After Opening" (PAO) symbol shall be included on the label to inform consumers.

13.2.5 BEST BEFORE DATE

13.2.5.1 The organisation shall ensure that the best before date is clearly indicated on the packaging, where required by regulations.

13.2.6 FUNCTION AND INSTRUCTIONS FOR USE

13.2.6.1 The organisation shall clearly define the product's intended function on the label.

13.2.6.2 Instructions for safe and effective use shall be included in a manner understandable to consumers.

13.2.7 NET MEASUREMENTS

13.2.7.1 The organisation shall declare the nominal value of the product volume or weight as per legal metrology requirements. Where the average weight system is used, compliance with the nominal value size requirements shall be ensured.

13.2.8 PRECAUTIONS AND WARNINGS

13.2.8.1 The organisation shall include any necessary safety warnings based on the product classification.

13.2.8.2 Compliance with regulatory hazard statements shall be ensured.

13.2.9 CRUELTY-FREE

13.2.9.1 The organisation shall obtain and maintain certification for cruelty-free claims.

13.2.9.2 Compliance with cruelty-free testing bans shall be **documented**.

13.2.10 ORGANIC CREDENTIALS

13.2.10.1 The organisation shall verify and maintain documentation for any organic certification claims made on the label.

13.2.11 DERMATOLOGICAL TESTING

13.2.11.1 The organisation shall support dermatological claims with clinical testing and maintain test reports.

13.2.12 **RECYCLING INFORMATION**

13.2.12.1 The organisation shall provide clear recycling instructions for packaging components.
13.2.12.2 Compliance with environmental labelling requirements shall be ensured.

13.3 **LEGALITY OF CLAIMS**

13.3.1 The following shall be checked:
- claims are not misleading and are fully in compliance with the Regulation on ingredient and allergens as well as other claims;
- ingredient calculations are in compliance with legislation and utilise EU-accepted methods for standardization
- active components are correctly calculated, taking into consideration moisture, assay, levels etc. such as 1% Salicylic acid;
- the dose of product in relation to intended claims is supported by scientific evidence;

TERMS AND DEFINITIONS

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Acceptance Criteria
Defined numerical limits, ranges, or other suitable parameters used to determine whether test results meet specified requirements.

Audit
A systematic and independent evaluation conducted to determine whether activities and related outcomes comply with planned arrangements, and whether these arrangements are effectively implemented and suitable for achieving defined objectives.

Batch
A specific quantity of raw material, packaging material, or product processed in one operation or a series of operations, expected to be homogeneous.

Batch Number
A unique identifier, comprising numbers, letters, or symbols, assigned to a batch for the purpose of traceability.

Bulk Product
A product that has completed all manufacturing stages up to, but not including, final packaging.

Calibration
A set of operations performed under specified conditions to establish the relationship between values indicated by a measuring instrument or system and the known values of a reference standard.

Cleaning
Operations intended to achieve a required level of cleanliness and visual appearance, involving the removal of visible dirt using a combination of chemical action, mechanical action, temperature, and time.

Complaint
An external communication indicating that a product may not meet defined acceptance criteria or customer expectations.

Concession
Formal authorization to deviate from specified requirements temporarily, due to planned or unplanned circumstances, within the scope of Good Manufacturing Practices.

Consumables
Materials such as cleaning agents, lubricants, and laboratory supplies that are used up during operations including cleaning, sanitization, maintenance, or testing.

Contamination
The unintended presence of any chemical, physical, or microbiological substance in a product, which may compromise its quality, safety, or efficacy.

Contract Acceptor
An individual, company, or external organization that performs a specific operation on behalf of another party (the contract giver), under agreed contractual terms.

Control
The process of verifying that specified acceptance criteria are met through inspection, testing, or monitoring.

Finished Product
A cosmetic product that has undergone all stages of production, including final packaging, and is ready for release and distribution.

GMP (Good Manufacturing Practices)
A system of guidelines that ensures products are consistently produced and controlled according to quality standards appropriate for their intended use and required by regulatory authorities.

GMP Control Zones
Designated areas subject to GMP requirements, including production, control, and storage areas, where activities must be carried out in compliance with quality and hygiene standards.

In-Process Control
Checks and measurements performed during production to monitor and, if necessary, adjust the process to ensure that the product meets defined specifications.

Internal Audit
A systematic and independent examination conducted by competent personnel within the organization to evaluate compliance with internal procedures and regulatory requirements.

Maintenance
Scheduled or unscheduled activities carried out to ensure that equipment, systems, and premises remain in a condition suitable for their intended use.

Major Equipment
Critical equipment identified in production or laboratory documentation that is essential for the proper execution of key processes.

Manufacturing Operation
The complete set of processes from the weighing of raw materials through to the production of the bulk product, prior to final packaging.

Organisation
The legal entity responsible for conducting activities at the operational location(s), including manufacturing, packaging, quality control, and distribution.

Out-of-Specification (OOS)
Any test result, measurement, or observation that falls outside of defined acceptance criteria.

Packaging Material
Materials used to contain, protect, handle, and present a product. These are categorized as:

- Primary packaging: in direct contact with the product.
- Secondary packaging: used to enclose primary packaging for identification or protection, not in direct contact with the product.

Packaging Operation
All steps required to convert a bulk product into a finished product, including filling, sealing, labeling, and final packaging.

Premises
The physical infrastructure, including buildings and defined internal/external boundaries, used for receipt, storage, processing, packaging, control, and dispatch of materials and products.

Production
The sequence of operations from filling and capping of the bulk product to final labeling and packaging into finished goods.

Quality Assurance (QA)
A comprehensive system of planned and systematic activities implemented to ensure that quality requirements for a product or process are fulfilled. Not to be confused with quality departments

Recall
A formal process initiated by an organization to withdraw a batch of product from the market due to quality, safety, or regulatory concerns.

Reprocessing
Re-treatment of a portion or entire batch of bulk or finished product that does not meet quality standards, in order to bring it back into compliance by repeating one or more production steps.

Return
The act of sending finished cosmetic products back to the manufacturing or distribution site, regardless of whether a quality defect is present.

Risk
The potential for a negative outcome or impact resulting from uncertainty.

Sample
One or more representative units selected from a batch or population to obtain information about the whole.

Sampling
A defined set of operations used to select, collect, and prepare samples for testing or evaluation.

Sanitization
A process used to reduce microbial contamination on surfaces to acceptable levels, depending on predefined objectives.
Note: This typically addresses contaminants not visible to the naked eye.

Shall
Indicates a mandatory requirement or obligation to carry out the specified activity.

Shipment
All operations involved in the preparation and dispatch of an order, including placement into transport vehicles.

Stock Items
Inventory materials including raw materials, packaging components (primary and secondary), bulk products, work-in-progress (WIP), and finished goods.

Technical Compliance
The assigned department responsible for ensuring the quality of the products is enforced, covering both QA and QC functions.

Traceability Code
A unique identifier, consisting of numbers, letters, or symbols, used to trace a specific batch throughout production and distribution.

Waste
Any material, residue, or by-product generated from a production, transformation, or usage operation that is no longer intended for use and is designated for disposal.