



APEXGLOBAL

QUALITY

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COS-GMP

002 - IMPLEMENTATION

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VERSION

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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 implementation was developed with the following key objectives:

- Providing a clear, stripped-down list of documents as a starting point for sites
- Provide a clear gap analysis for sites as part of their audit-ready inspection.
- Potentially provide a framework for site's internal audit programme.

What this document is not, is a consultation guide on COS-GMP.

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

2.0

REFERENCES

2.0 REFERENCES

- COS-GMP - 001 Standard

3.0

REQUIRED DOCUMENTS

3.0 REQUIRED DOCUMENTS

3.1 GENERAL

This list outlines the required documents per the COS-GMP standard for implementing GMP-MS. It serves as guidance only; the COS-GMP standard's wording supersedes this document and is enforceable as it cannot be guaranteed that this list is 100% complete.

| Clause | Section | Document |
|----------|-------------------------------------|--|
| 3 | Documentation | |
| 3.1.1 | Documentation | Procedure for documentation |
| 3.1.1 | Documentation | List of documents |
| 3.1.1 | Documentation | Change control records |
| 3.1.2 | Documentation | Records of back ups |
| 3.3.3 | Documentation | Documented retention periods for records |
| 3.4.1 | Electronic Documentation | Procedure for electronic software validation |
| 3.4.3 | Electronic Documentation | Contracts with electronic software providers |
| 4 | Risk Management | |
| 4.1.2.1 | Hazard analysis risk assessment | Procedure for the Hazard analysis risk assessment |
| 4.1.2.1 | Hazard analysis risk assessment | HARA record per product group |
| 4.1.3.1 | Chemical Control | Approved Materials Register |
| 4.1.4.1 | Foreign Body Control | Procedure for identifying, controlling and managing potential foreign body risks |
| 4.1.5.1 | Glass and brittle materials | GBM register |
| 4.1.6.1 | Sharps and metal control | Procedure for use of sharp tools, such as knives, blades, needles, and wires to prevent stock item contamination |
| 4.1.6.1 | Sharps and metal control | Sharps and metal control records |
| 4.2.1 | Personnel risk assessments | Risk assessment programme for personnel |
| 5 | GMP Management System | |
| 5.1.1.1 | Non-Conformances | Procedure for Non-conformances |
| 5.1.1.1 | Non-Conformances | Records of Non-conformances |
| 5.1.4.1 | Corrective and Preventative actions | Procedure for Corrective and Preventative actions |
| 5.1.4.1 | Corrective and Preventative actions | Records of Corrective and Preventative actions |
| 5.2.1.1 | Concessions | Procedure for Concessions |
| 5.2.1.1 | Concessions | Records of Concessions |
| 5.3.1.2 | Traceability | Procedure for Traceability |
| 5.2.1.1 | Traceability | Records of Traceability |
| 5.3.1.4 | Traceability | Traceability evaluation/simulation |
| 5.4.1.1 | Complaints | Procedure for Complaints |
| 5.4.1.1 | Complaints | Records of Complaints |
| 5.4.1.7 | Complaints | Trends for Complaints |
| 5.5.1.1 | Recalls | Procedure for Recall |

| Clause | Section | Document |
|----------|---|--|
| 5.5.1.1 | Recalls | Records of Recall |
| 5.5.1.8 | Recalls | Recall evaluation/simulation |
| 5.6.1.3 | Subcontracting and Outsourcing | Contract or agreements |
| 5.6.2.1 | Supplier Approval | Procedure for supplier approval |
| 5.6.2.1 | Supplier Approval | ASL register |
| 5.6.3.1 | Purchasing | Procedure for purchasing |
| 5.6.3.4 | Purchasing | Records of purchases |
| 5.8.1.1 | Internal Audits | Procedure for internal audits |
| 5.8.1.1 | Internal Audits | Records of internal audits |
| 5.8.1.2 | Internal Audits | Internal Audits Programme/Schedule |
| 6 | Personnel | |
| 6.1.1 | Personnel | Documented evidence of who is Senior Management |
| 6.1.2 | Personnel | GMP Policy |
| 6.2.2 | Responsibilities | Personnel Responsibilities |
| 6.3.1 | Organisation | Organisation Chart |
| 6.3.2 | Organisation | List of Deputies |
| 6.4.1 | Competence and Training | Procedure for training |
| 6.4.2 | Competence and Training | Records of training |
| 6.5.1.1 | Personnel Hygiene | Procedure for personnel hygiene |
| 6.2.2 | Visitors | Records of visitors health status |
| 7 | Premises and Site Standards | |
| 7.1.3 | Premises and Site Standards | Site plan |
| 7.4.3 | Infrastructure | Windows of glass inspections |
| 7.6.1 | Premises and Site Standards - Cleaning and Sanitization | Procedure for cleaning and sanitization including the programme/schedule |
| 7.6.2 | Premises and Site Standards - Cleaning and Sanitization | Records of cleaning and sanitization for the site |
| 7.7.1 | Maintenance | Preventative maintenance programme |
| 7.7.1 | Maintenance | Records of preventative maintenance |
| 7.7.2 | Maintenance | Contracts with all maintenance service providers |
| 7.9.1 | Pest Control | Pest control programme |
| 7.9.1 | Pest Control | Contract with pes control provider |
| 7.9.1 | Pest Control | Pest control records |
| 7.10.6 | Waste | Records of waste handling and removal |
| 8 | Equipment | |
| 8.3.1 | New Equipment Acceptance | Records of new equipment acceptance |
| 8.4.1 | Calibration | Procedure for calibration |
| 8.4.4 | Calibration | Records of calibration |
| 8.5.1 | Cleaning and Sanitization | Procedure for cleaning activities |
| 8.5.2 | Cleaning and Sanitization | Records of cleaning |
| 8.6.1 | Maintenance | Preventative maintenance programme |

| Clause | Section | Document |
|-----------|------------------------------------|---|
| 8.6.1 | Maintenance | Records of preventative maintenance |
| 8.6.2 | Maintenance | Contracts with all maintenance service providers |
| 9 | Purchasing and Goods Intake | |
| 9.1.1 | General | Procedure for received items and services |
| 9.1.2 | General | Specifications for stock items |
| 9.2 | Goods Intake | Delivery notes and purchase orders |
| 9.4 | Release | Procedure for stock item release |
| 9.5.1 | Water used as a stock item | Documents for water treatment |
| 9.5.1 | Water used as a stock item | Records for water treatment |
| 10 | Production | |
| 10.1.1 | General | Procedure for production controls (See 10.2.1.2 & 10.3.1.2) |
| 10.2.1.2 | Bulk Manufacturing | Specification for bulk |
| 10.2.2.1 | Bulk Manufacturing | Records for Pre-start clearance |
| 10.2.5.2 | Bulk Manufacturing | Records of in-process controls |
| 10.3.1.2 | Filling and Packing | Specification for product |
| 10.3.2.1 | Filling and Packing | Records for Pre-start clearance |
| 10.3.5.2 | Filling and Packing | Records of in-process controls |
| 11 | Storage and Despatch | |
| 11.1.1 | General | Procedure for stock item storage, release, dispatch and returns |
| 11.3.1 | Re-evaluations and Shelf life | Procedure for Shelf life/expiration of stock items |
| 11.3.2 | Re-evaluations and Shelf life | Records of shelf-life extensions |
| 12 | Inspections and Acceptance | |
| 12.2.2 | Test Methods | Procedures for test methods |
| 12.3.2 | Acceptance Criteria | Records of testing and acceptance |
| 12.4.2 | Analytical Materials | Procedures for the preparation of analytical solutions |
| 13 | Design and Development | |
| 13.1.1.1 | General | Procedure for design and development of products |
| 13.1.2.1 | Brief | Records of design and development activities – Brief |
| 13.1.4.1 | Recipe | Records of design and development activities – Recipe |
| 13.1.5.1 | Methodology | Records of design and development activities – Methodology |
| 13.1.6.2 | Stability | Records of design and development activities – Stability |
| 13.1.8.2 | Preservation | Records of design and development activities - Preservation |
| 13.1.9.6 | Release | Records of design and development activities – Legal Release to Ops |
| 13.2.9.2 | Cruelty free | Records of design and development activities – Cruelty free |
| 13.3.1 | Claims | Records of design and development activities - Claims |

4.0

AUDIT GAP ANALYSIS

4.0 AUDIT READY - GAP ANALYSIS

4.1 GENERAL

The following is a general Gap analysis which can be used to gauge your sites audit ready status.

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|--|-----------------------|-------------------|
| 3 | DOCUMENTATION | | |
| 3.1.1 | Has the organisation defined controls for documentation through a documented procedure , including: | Procedure Ref: | |
| | - 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 | | |
| 3.1.2 | - a system for replacing updated documents and informing relevant personnel | | |
| | Where documents and records are in electronic form are these: | | |
| | - stored securely | Location: | |
| | - backed up | Back-up Policy: | |
| | - be easily accessible to ensure traceability. | Method: | |
| | Control of Documents | | |
| 3.2.1 | Are documents 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 | Do documents contain, at minimum; | | |
| | - a title, which should be unambiguous | | |
| | - a unique reference | | |
| | - a version | | |
| | - an author | | |
| | - the date of approval. | | |
| 3.2.3 | Are documents: | | |
| | - 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 | Are documents updated, when necessary, and the version number indicated? Is the reason for each revision retained and previous versions archived? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|--------|---|-----------------------|-------------------|
| 3.2.5 | Is the duration of archiving original documents defined according to applicable legislation and regulations? | Duration: | |
| 3.2.6 | Is the storage of archived documents properly secure? | Method: | |
| 3.2.7 | Are documents archived as either electronic or hard-copies and their legibility ensured? | | |
| | Control of Records | | |
| 3.3.1 | Are all records legible, appropriately authorised, retained in good condition, and easily retrievable? | | |
| 3.3.2 | For handwritten data entries, do records: | | |
| | - clearly indicate what must be entered? | | |
| | - use permanent ink and be written legibly? | | |
| | - include approval and date? | | |
| | - document corrections legibly, with authorisation and justification? | | |
| | - avoid ambiguous declarations (e.g. unexplained ticks)? | | |
| | - avoid blank fields where "N/A" or similar should be used? | | |
| 3.3.3 | Is the retention period for records documented based on the product's usable life, intended use, and legal/customer requirements? | | |
| | Electronic Documentation | | |
| 3.4.1 | Is there a documented procedure for validating software used in the GMP system, proportionate to the associated risk? | Procedure Ref: | |
| 3.4.1 | Does the validation plan ensure: | | |
| | - protection to ensure correct data entry? | | |
| | - backup system to retrieve data in case of alteration or loss? | | |
| | - protection against unauthorised data access? | | |
| | - procedures for issue, cancellation or change of authorisation? | | |
| | - procedures for system failure/breakdown response? | | |
| 3.4.2 | Are critical electronic systems (e.g., document storage, stock control) access- and change-restricted to authorised personnel only? | | |
| 3.4.3 | If subcontractors manage IT activities, is there a signed contract detailing roles and controls? | | |
| 3.4.4 | Are there alternative arrangements in case of IT system failure, including: | | |
| | - backup and protection of electronic records? | | |
| | - functional alternatives for offline operation? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|---|-----------------------|-------------------|
| 4 | RISK ASSESSMENTS | | |
| | General | | |
| 4.1.1.1 | Have all practicable steps been taken to identify, eliminate, avoid, or minimise risks of foreign-body or chemical contamination? | | |
| | Hazard Analysis Risk Assessment (HARA) | | |
| 4.1.2.1 | Is there a documented procedure with records showing that all hazards are identified and controlled? | Procedure Ref: | |
| 4.1.2.2 | Has a multi-disciplinary HARA team been assembled including relevant domain experts? | | |
| 4.1.2.3 | Is there a documented product description covering: name, intended use, key ingredients, storage, handling, shelf life, and special conditions? | | |
| 4.1.2.4 | Is there a verified and updated process flow diagram covering all stages from raw material receipt to distribution (including rework/returns)? | | |
| 4.1.2.5 | Has a hazard analysis been completed at each step, assessing likelihood, severity, and control measures for biological, chemical, physical, and allergenic hazards? | | |
| 4.1.2.6 | Are QCPs and CCPs clearly identified within the HARA? | | |
| 4.1.2.7 | Is a logical decision process (e.g. decision tree) used to determine CCPs? | | |
| 4.1.2.8 | Are each CCP's control measures, critical limits, monitoring, and corrective actions defined? | | |
| 4.1.2.9 | Is a risk-based approach used to define QCPs, based on internal quality requirements? | | |
| 4.1.2.10 | Are QCPs defined with control measures, limits, monitoring, and corrective actions? | | |
| 4.1.2.11 | Are procedures in place to monitor the effectiveness of hazard controls (e.g. inspections, verification, reviews)? | | |
| 4.1.2.12 | Are all HARA activities documented and maintained (e.g. team records, reports, diagrams, validations)? | | |
| | Chemical Control (AMR – Approved Materials Register) | | |
| 4.1.3.1 | Is there a maintained AMR including approved chemicals, SDS availability, label identification, scent controls, and restricted access to storage? | | |
| | Foreign Body Control | | |
| 4.1.4.1 | Are documented procedures for foreign bodies implemented based on risk? | Procedure Ref: | |
| 4.1.4.2 | Are GMP zones free from uncontrolled foreign body risks? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------------|-------------------|
| | Glass and Brittle Materials Control | | |
| 4.1.5.1 | Is there a register of glass/brittle items (with type, condition, location, risk level), including those outside production areas where appropriate? | | |
| 4.1.5.2 | Are risk-based condition checks of these items done at defined intervals and recorded? | | |
| 4.1.5.3 | Are issues promptly recorded and corrective actions implemented? | | |
| | Sharps and Metal Control | | |
| 4.1.6.1 | Are sharp tool controls documented and include issue tracking and breakage records? | | |
| 4.1.6.2 | Is the use of snap-off blades strictly prohibited? | | |
| | 4.1.7 – Other Controls | | |
| 4.1.7.1 | Are labels on equipment securely affixed and easy to clean? | | |
| 4.1.7.2 | Are wooden items in production areas sealed and maintained in good condition to prevent contamination? | | |
| 4.1.7.3 | Are staples, clips, and pins prohibited in open product areas, with suitable controls where used for packaging? | | |
| 4.1.7.4 | Are handheld devices managed to prevent physical contamination? | | |
| | Product Contamination Control | | |
| 4.2.1 | Has a documented Personnel Risk Assessment Program been established and maintained? | Risk Assessment Ref: | |
| | Is the program reviewed at least annually? | | |
| | Does the risk assessment framework inform the hygiene programme outlined in section 6.5? | | |
| 4.2.2 | Are health and hygiene risks (e.g., illness, infections, wounds) assessed? | | |
| | Are behavioural risks (e.g., non-compliance with procedures) evaluated? | | |
| | Are physical contamination risks from personal items (e.g., jewellery, watches) assessed? | | |
| | Are zoning risks (e.g., unauthorized access to high-risk areas) included in the assessment? | | |
| | Are training-related risks (e.g., lack of hygiene awareness) considered? | | |
| 4.2.3 | Are hygiene and medical screening checks routinely conducted as required? | | |
| | Is the use of PPE (e.g., gloves, hairnets, uniforms) mandatory and based on risk assessment findings? | | |
| | Is access to high-risk zones controlled based on training and authorization? | | |
| | Is there an enforced policy prohibiting jewellery, watches, and personal items in processing areas? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|--|-----------------------|-------------------|
| | Are supervisors or leadership personnel monitoring hygiene and safety compliance? | | |
| 5 | GMP SAFETY AND QUALITY MANAGEMENT | | |
| | Non-Conformances | | |
| 5.1.1.1 | Are there documented procedures in place to define the control of non-conformances? | Procedure Ref: | |
| 5.1.1.1 | Are records of non-conformances maintained? | | |
| 5.1.1.2 | Do non-conformance controls cover materials, bulk, product, and general compliance failures across the GMP system? | | |
| 5.1.1.2 | Are affected stock items effectively identified and managed before disposition decisions are made? | | |
| 5.1.1.3 | Are non-conforming stock items reviewed periodically or at least annually for trends or recurring issues? | | |
| 5.1.2.1 | Are non-conforming stock items clearly identified and managed to prevent unauthorized release? | | |
| 5.1.2.2 | Are non-conforming items assessed and disposition decisions (reject, rework, concession, etc.) documented and recorded? | | |
| 5.1.2.3 | Are destruction or reprocessing decisions approved by Technical Compliance and, where applicable, the customer? | | |
| 5.1.2.4 | Is the reprocessing method clearly defined and approved? | | |
| 5.1.2.4 | Are inspections conducted on reprocessed items, and results reviewed to verify conformity to acceptance criteria? | | |
| 5.1.3.1 | Is there an effective communication system to notify suppliers of non-conforming stock items? | | |
| 5.1.3.2 | Do suppliers conduct root cause analyses and provide corrective action responses in a timely manner? | | |
| | Corrective and preventative actions (CAPA/VA) | | |
| 5.2.1 | Is there a documented procedure defining controls for recording, handling, and correcting issues in the GMP and stock item safety system? | Procedure Ref: | |
| 5.2.2 | Do site procedures require completion of corrective actions, root cause analysis, and preventive actions within appropriate timescales? | | |
| 5.2.3 | Are investigations conducted and recorded when stock item safety or legality is at risk, or adverse quality trends are identified? | | |
| 5.2.3 | Does the investigation include: | | |
| | - Clear documentation of the issue? | | |
| | - Defined corrective actions to address the immediate problem? | | |
| | - Appropriate timescales for completion of corrective and preventive actions? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------|-------------------|
| | - Assigned responsibility for actions? | | |
| | - Verification that the actions were implemented and effective? | | |
| | Concessions | | |
| 5.3.1.1 | Are there documented procedure in place defining controls for concessions, with records maintained? | Procedure Ref: | |
| 5.3.1.2 | Are all deviations from specified requirements supported by sufficient data and authorised by Technical Compliance with no conflict of interest? | | |
| 5.3.1.3 | Are corrective actions taken to prevent recurrence of concessions where trends are identified or applicable? | | |
| 5.3.1.4 | Are concessions reviewed periodically, or at least annually, to identify trends or recurring issues, and are these reviews documented? | | |
| | Traceability | | |
| 5.4.1.1 | Can the organisation trace all raw materials through manufacturing (including outsourced operations) to the customer, and in reverse? | | |
| 5.4.1.2 | Is there a documented procedure that describes how traceability is maintained throughout operations? | | |
| 5.4.1.2 | Does the procedure define stock item identification systems (e.g. labelling and coding for raw materials, WIP, and finished goods)? | | |
| 5.4.1.3 | Is identification of raw materials, WIP, finished products, non-conforming and quarantined items adequate to ensure traceability? | | |
| 5.4.1.4 | Is the traceability process evaluated at least annually, including the procedure's accuracy and record completeness (for both forward and backward)? | | |
| | Complaints | | |
| 5.5.1.1 | Is there a documented procedure defining controls for complaints, with records maintained? | Procedure Ref: | |
| 5.5.1.2 | Are all complaints recorded and investigated, with actions taken based on seriousness and frequency where sufficient information is provided? | | |
| 5.5.1.3 | For contracted operations, has the process for managing complaints been agreed upon by both the contract giver and acceptor? | | |
| 5.5.1.4 | Are complaints and associated data centralised by authorised personnel, including customer communication, reports, root cause actions, and regulatory notifications? | | |
| 5.5.1.5 | Is appropriate follow-up conducted on the affected batch(es)? | | |
| 5.5.1.6 | Do investigations include: | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------|-------------------|
| | - Corrective actions for the defect (where appropriate)? | | |
| | - Preventive actions to avoid recurrence? | | |
| | - Checks of other potentially affected batches? | | |
| 5.5.1.7 | Are complaint trends or repeat issues reviewed periodically (at least annually), and are records of the review maintained? | | |
| | Recalls | | |
| 5.6.1.1 | Is there a documented procedure defining controls for product recalls, with records maintained? | Procedure Ref: | |
| 5.6.1.2 | When a recall is initiated, are steps taken to ensure full traceability, accountability of affected stock, and implementation of corrective actions? | | |
| 5.6.1.3 | For contracted operations, is the recall process agreed upon and documented in the contract between the giver and acceptor? | | |
| 5.6.1.4 | Is the recall process coordinated by a designated recall team or authorised personnel? | | |
| 5.6.1.5 | Are recall operations initiated promptly, completed in a timely manner, and do they account for all affected stock? | | |
| 5.6.1.6 | Are appropriate authorities notified in the event of recalls that may affect consumer safety? | | |
| 5.6.1.7 | Are recalled products identified and securely stored separately while awaiting a final decision? | | |
| 5.6.1.8 | Is the product recall process evaluated at least annually via a mock recall, with key timings and staff awareness of responsibilities recorded? | | |
| | PROCUREMENT AND SUBCONTRACTING | | |
| | Subcontracting And Outsourcing | | |
| 5.7.1.1 | Are subcontracted activities (e.g., manufacturing, packaging, sorting, rework) clearly defined and controlled? | | |
| 5.7.1.2 | Are outsourced services (e.g., pest control, cleaning, transport, labs, calibration, consultants) clearly defined and included in GMP control scope? | | |
| 5.7.1.3 | Is there a written contract or agreement between the contract giver and acceptor for all subcontracted activities? | | |
| 5.7.1.4 | Does the contract specify the duties and responsibilities of both parties clearly and in writing? | | |
| 5.7.1.5 | Can the organisation demonstrate that off-site subcontracted activities are declared to customers and approved where required? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------|-------------------|
| 5.7.1.6 | Is the contract acceptor evaluated for capability, capacity, and compliance before contracting? Are oversight measures (e.g., inspections, positive release) in place? | | |
| 5.7.1.7 | Does the contract or specification include all information required for correct execution (traceability, handling requirements, etc.)? | | |
| 5.7.1.8 | Is prior written approval from the contract giver required before any work is further subcontracted? Are formal controls in place for such third-party arrangements? | | |
| | Supplier Approval | | |
| 5.7.2.1 | Is there a documented procedure for supplier approval, including maintenance of an approved supplier register with status, scope, and risk-based evaluation? | Procedure Ref: | |
| 5.7.2.2 | Is the initial approval of manufacturing sites for raw materials risk-based and approved by a competent person? | | |
| 5.7.2.2 | Are the following approval methods used and justified where applicable: | | |
| | - Valid certification to product safety standards (e.g. ISO, BRC) with relevant scope? | | |
| | - Certification to a QMS covering traceability and safety (e.g. declarations of compliance)? | | |
| | - Supplier audits assessing QMS, traceability, and controls with complete reports by qualified personnel? | | |
| 5.7.2.2 | - Risk-justified Supplier Approval Questionnaires (SAQs) covering product safety systems, traceability, and controls? | | |
| | | | |
| 5.7.2.3 | If none of the above apply, is there a defined and justified alternative process to ensure product quality, safety, and legality from unapproved sources? | | |
| 5.7.2.4 | Are suppliers of services (subcontracting/outsourcing) approved and monitored under a documented procedure with records maintained? | | |
| 5.7.2.5 | Is the frequency of supplier approval and monitoring based on: | | |
| | - Product safety and quality risk? | | |
| | - Compliance with legal requirements? | | |
| | - Risks identified in vulnerability and product defence assessments? | | |
| | Purchasing | | |
| 5.7.3.1 | Is there a documented procedure defining controls for purchasing goods and services? | Procedure Ref: | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------|-------------------|
| 5.7.3.2 | Are purchases only made from suppliers and service providers who have been assessed and approved? | | |
| 5.7.3.3 | Are purchase orders issued to approved suppliers and do they include: | | |
| | - Description of the goods or services? | | |
| | - Quantity required? | | |
| | - Delivery timelines as specified by the organisation? | | |
| 5.7.3.4 | - Relevant organisational requirements (e.g., specifications, compliance needs)? | | |
| | Are records of all purchases, including purchase orders, maintained? | | |
| | Change Control | | |
| 5.8.1 | Are changes that could affect the quality of stock items assessed and approved by authorised personnel based on sufficient data? | | |
| | Internal Audits | | |
| 5.9.1.1 | Is there a documented procedure for internal audits in place that includes: | Procedure Ref: | |
| | - Minimum annual audit frequency? | | |
| | - Defined scope of each audit? | | |
| | - Completion of audit records? | | |
| | - Assigned internal auditors for each audit? | | |
| | - Senior management review and acknowledgement of audit outcomes? | | |
| 5.9.1.2 | - Method for recording/managing non-conformities identified in audits? | | |
| | Are internal system audits performed against COS-GMP clauses to confirm conformance to: | | |
| | - The organisation's own procedures? | | |
| | - The COS-GMP Standard itself? | | |
| 5.9.1.3 | - Effective implementation and maintenance of the GMP system? | | |
| | Are audits conducted by competent designated personnel or under supervision, and are auditors independent, objective, and trained? | | |
| 5.9.1.4 | Are all audit findings (positive and negative) recorded, including: | | |
| | - Objective evidence? | | |
| | - Evidence of conformity and nonconformity, with risk rating? | | |
| 5.9.1.5 | - Potential nonconformities and improvement opportunities? | | |
| | Does audit follow-up confirm that corrective actions are completed and implemented effectively? | | |
| 5.9.1.6 | Is the internal audit programme fully implemented and maintained? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|--|----------------------|-------------------|
| 6 | PERSONNEL | | |
| | General | | |
| 6.1.1 | Has the organisation documented who qualifies as “Senior Management” (including the most senior managers)? | Document Ref: | |
| 6.1.2 | Has Senior Management documented and published a GMP policy that reflects company culture, is easy to understand, and is communicated to all personnel? | | |
| 6.1.3 | Is the GMP programme demonstrably supported by Senior Management? | | |
| 6.1.4 | Has management defined and communicated which personnel are authorised to access specific areas? | | |
| | Responsibilities of Personnel | | |
| 6.2.1 | Do all personnel: | | |
| | - Know their position in the organisational structure? | | |
| | - Know their defined responsibilities and tasks? | | |
| | - Have access to and comply with documents relevant to their role? | | |
| | - Comply with personal hygiene requirements? | | |
| | - Feel encouraged and enabled to report irregularities or non-conformities? | | |
| 6.2.2 | Has Senior Management documented roles and authorities related to GMP, including: | | |
| | - A clear statement on the importance of GMP and individual responsibility? | | |
| | - Who is responsible for implementing each procedure? | | |
| | - Who is authorised to represent the GMP system to third parties? | | |
| 6.2.3 | Has Senior Management ensured personnel are granted the authority necessary to carry out their assigned responsibilities? | | |
| | Organisation | | |
| 6.3.1 | Is there a documented organisational chart (organogram) showing the structure of personnel, including Technical Compliance as independent from Production? | | |
| 6.3.2 | Are deputies clearly assigned and documented for all key roles? | | |
| 6.3.3 | Are staffing levels across all operational areas adequate for the size, scope, and complexity of the organisation (including contractors and temporary workers)? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|---------|--|-----------------------|-------------------|
| | Competence & Training | | |
| 6.4.1 | Is there a documented procedure defining the training programme and its controls? | Procedure Ref: | |
| 6.4.2 | Are training needs identified for all personnel and maintained in a formal training programme with full training records? | | |
| | Do training records include: | | |
| | - Name of trainee and physical/digital attendance confirmation? | | |
| | - Date and duration of training? | | |
| | - Training title, procedure, or course content? | | |
| | - Internal or external provider name? | | |
| 6.4.3 | Is training treated as an ongoing, regularly updated process with records maintained? | | |
| 6.4.4 | Do all personnel, including temporary workers and contractors, receive proper training before starting work and are adequately supervised? | | |
| 6.4.5 | Are company inductions conducted for all personnel and do they include hygiene rules, GMP policy, responsibilities, and awareness of company requirements? | | |
| 6.4.6 | Do all personnel receive GMP awareness training at least annually? | | |
| 6.4.7 | Is additional training (on-the-job, skill improvement, process enhancement) provided as needed to maintain product and process quality? | | |
| | PERSONNEL HYGIENE AND HEALTH | | |
| | Personnel Hygiene | | |
| 6.5.1.1 | Is there a documented hygiene programme adapted to organisational needs and supported by the personnel risk assessment programme? | Document Ref: | |
| 6.5.1.1 | Do all personnel entering GMP Control Zones understand and follow hygiene requirements? | | |
| 6.5.1.2 | Are hand-washing facilities suitably located, sufficient, and used regularly before and after key activities (e.g., breaks, toilet, smoking)? | | |
| | Do hand-washing stations provide: | | |
| | - Adequate water at a suitable temperature? | | |
| | - Suitable hand-drying facilities? | | |
| | - Signage prompting handwashing? | | |
| 6.5.1.3 | Do all personnel wear appropriate clothing and protective garments in GMP zones, stored separately from personal clothing? | | |
| 6.5.1.4 | Are eating, drinking (except controlled water stations), and smoking prohibited in GMP zones based on risk assessment? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|---|----------|-------------------|
| 6.5.1.5 | Is personal medication in GMP zones avoided or managed through case-by-case risk assessments? | | |
| 6.5.1.6 | Are unhygienic practices prohibited in GMP areas as defined in the hygiene programme? | | |
| | Personnel Health | | |
| 6.5.2.1 | Are ill or injured personnel excluded from stock item contact until medically cleared or the risk to product quality is ruled out? | | |
| | Visitors, Contractors And Untrained Personnel | | |
| 6.6.1 | Are visitors and untrained personnel preferably excluded from GMP zones or supervised and informed in advance (e.g., hygiene and protective clothing)? | | |
| 6.6.2 | Is a health status evaluation system in place for visitors and contractors prior to site access, with records maintained (e.g., via a visitor questionnaire)? | | |
| 7 | PREMISES & SITE STANDARDS | | |
| | General | | |
| 7.1.1 | Are premises located, designed, constructed, and used to: - protect stock items? - permit efficient cleaning and maintenance? - minimize mix-ups? | | |
| 7.1.2 | Are design decisions based on product type, existing conditions, and cleaning/sanitizing measures? | | |
| 7.1.3 | Does the organisation have a documented and up-to-date site plan in place? | | |
| | Control Zones | | |
| 7.2.1 | Are GMP control zones and their risk status clearly defined and documented on the site plan? | | |
| 7.2.2 | Are separate or defined areas provided for: - storage - production - quality control - ancillary areas - washing and toilets? | | |
| 7.2.3 | Is clear signage provided for GMP zones to ensure personnel understand the applicable restrictions and controls? | | |
| | Flow | | |
| 7.3.1 | Is the flow of stock items, personnel, and waste clearly defined and documented on the site plan to prevent mix-ups and reduce contamination risks? | | |
| 7.3.1 | Is the layout from intake to dispatch organized to prevent contamination or damage to stock items? | | |
| 7.3.2 | Is there sufficient space for receipt, storage, and production to prevent mix-ups and support safe, hygienic operations? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|--------|--|----------|-------------------|
| | Infrastructure | | |
| 7.4.1 | Are design risks considered for walls, floors, ceilings, doors, windows, overhead beams, pipes, and ducts to prevent contamination and allow cleaning access? | | |
| 7.4.2 | Are floors, walls, ceilings, and windows in GMP zones designed for easy cleaning/sanitizing, and maintained in good repair? | | |
| 7.4.3 | Are windows protected, regularly checked for breakage, and screened if open to outside? Are checks documented per a risk assessment? | | |
| 7.4.4 | Are floors hard-wearing, undamaged, and resistant to cleaning materials/methods (no flaking, delamination, or poor repairs)? | | |
| 7.4.5 | Is sufficient lighting provided to ensure process control, inspection, and safe/clean work environments? | | |
| 7.4.6 | Is suitable ventilation provided and maintained to control condensation, dust, heat, and fumes? | | |
| 7.4.7 | Are pipework, ducts, drains, and guttering maintained to prevent drips/leaks and contamination of stock or equipment? | | |
| 7.4.8 | Are internal/external drains clean, unblocked, and protected from backflow? | | |
| 7.4.9 | Is pooling water avoided, and where present, are corrective actions recorded and addressed promptly? | | |
| | Staff Facilities (Break Rooms, Locker Rooms, Changing Rooms, Washing Rooms And Toilets) | | |
| 7.5.1 | Are suitable, clean staff facilities provided and separated from production/storage areas, with showers/changing rooms as needed for hygiene? | | |
| 7.5.2 | Are personal belongings stored away from products, storage, and eating areas and do not contact GMP-required PPE? | | |
| 7.5.3 | Are vending/catering food services provided in a way that does not pose a health risk to staff? | | |
| 7.5.4 | Do cleaning activities within staff facilities use dedicated (e.g., colour-coded) cleaning equipment that is separate from GMP Control Zones? | | |
| | Cleaning and Sanitization | | |
| 7.6.1 | Is there a documented cleaning and sanitization procedure/schedule for all areas (GMP zones, staff facilities, offices) including: - Equipment and materials used - Dilutions from AMR - Required contact times? | | |
| 7.6.2 | Is the site maintained in a clean condition, with cleaning activities recorded (especially in GMP zones), and free of contamination risk? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|--------|---|----------|-------------------|
| 7.6.3 | Are cleaning and sanitizing activities validated to ensure material effectiveness at defined dilutions/contact times? | | |
| 7.6.4 | Is all cleaning equipment clean, maintained, and in good repair? | | |
| | Maintenance | | |
| 7.7.1 | Is there a documented preventative maintenance programme in place, and are maintenance records maintained? | | |
| 7.7.2 | If subcontractors are used, is there a signed, documented agreement defining how maintenance activities are managed? | | |
| | Consumables | | |
| 7.8.1 | Are consumables used in premises (e.g., for cleaning, maintenance) controlled to ensure they do not affect stock quality? | | |
| | Pest Control | | |
| 7.9.1 | Is there a signed pest control agreement and programme in place, with records acknowledged by both provider and internal responsible personnel? | | |
| 7.9.2 | Are premises designed, built, and maintained to prevent pest ingress? | | |
| 7.9.3 | Are exterior premises controlled to prevent attraction or harbouring of pests? | | |
| 7.9.4 | Are corrective actions from pest control inspections implemented within the timeframe given by the provider, and recorded? | | |
| 7.9.5 | Is pest control activity conducted in compliance with applicable laws and legislation? | | |
| | Waste | | |
| 7.10.1 | Is waste disposed of promptly and hygienically without posing risk to stock items? | | |
| 7.10.2 | Are waste types that could affect stock item quality identified using production and QC lab findings? | | |
| 7.10.3 | Is waste flow managed to avoid disruption or contamination of production and lab areas? | | |
| 7.10.4 | Are there appropriate measures for waste collection, transport, storage, and disposal? | | |
| 7.10.5 | Are waste containers properly closed, labelled, and identified with contents and relevant information? | | |
| 7.10.6 | Where legally required, is waste removed by licensed contractors, and are removal records maintained and audit-ready? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|--------|---|-----------------------|-------------------|
| 8 | EQUIPMENT | | |
| | General | | |
| 8.1.1 | Is equipment suitable for its intended purpose, cleanable, and if needed, sanitizable and maintainable (e.g., CIP systems considered)? | | |
| 8.1.2 | Is major equipment readily identifiable and defined? | | |
| | Equipment design and placement | | |
| 8.2.1 | Is operational equipment designed to prevent stock item contamination? | | |
| 8.2.2 | Are bulk product containers protected from airborne contamination (e.g., dust, moisture)? | | |
| 8.2.3 | Are unused hoses and accessories cleaned, sanitized if needed, sealed, and protected from contamination? | | |
| 8.2.4 | Are equipment materials compatible with stock items and cleaning/sanitizing agents (e.g., greases, oils)? | | |
| 8.2.5 | Is equipment placed to ensure personnel or item movement does not cause quality risks? | | |
| 8.2.6 | Is sufficient access available for cleaning and maintenance under/around/inside equipment? | | |
| | New equipment acceptance | | |
| 8.3.1 | Is new equipment assessed for GMP suitability, with risks, cleaning, maintenance, and procedures defined and documented (e.g., FAT/validation)? | | |
| | Calibration | | |
| 8.4.1 | Is there a documented procedure for calibration in place? | Procedure Ref: | |
| 8.4.2 | Are in-line and off-line measuring devices identified and controlled, including: - Equipment register and location - ID codes and due dates - Calibration records - Protection from misuse and unauthorised adjustment? | | |
| 8.4.3 | Is equipment accuracy specified with permitted tolerances based on product parameters? | | |
| 8.4.4 | Is calibration conducted at a set frequency by trained personnel with defined methods and documented results? | | |
| 8.4.5 | Are out-of-spec instruments removed from service, investigated for stock item impact, and corrective actions taken as needed? | | |
| | Cleaning and Sanitization | | |
| 8.5.1 | Is there a documented cleaning and sanitization procedure for equipment, including: - Equipment | Procedure Ref: | |

| Clause | Checklist Item | Evidence | Compliance Status |
|------------|--|----------|-------------------|
| | & materials used - Dilutions (AMR) - Contact times? | | |
| 8.5.2 | Is all equipment maintained in clean condition, with cleaning activities recorded? | | |
| 8.5.3 | Are cleaning/sanitizing activities validated to confirm effectiveness at defined concentrations and contact times? | | |
| 8.5.4 | Is cleaning equipment itself clean and in good repair? | | |
| | Maintenance | | |
| 8.6.1 | Is there a signed contract/agreement with any maintenance subcontractor where applicable? | | |
| 8.6.2 | Is equipment maintained through a preventative maintenance programme with records of activities? | | |
| 8.6.3 | Is defective equipment clearly identified, removed from use, and isolated if possible? | | |
| 8.6.4 | Are maintenance activities conducted in a way that does not affect stock item quality? | | |
| | Consumables | | |
| 8.7.1 | Are consumables used in equipment (e.g., filters, gaskets, lubricants) verified not to compromise product quality? | | |
| | Authorisation and Access | | |
| 8.8.1 | Are equipment and automated systems accessed and operated only by authorised personnel? | | |
| 8.8.2 | Where passwords are used, are they secured against unauthorised access? | | |
| 9.0 | PURCHASING AND GOODS INTAKE | | |
| | General | | |
| 9.1.1 | Is verification of received items and services conducted in accordance with a documented procedure ? | | |
| 9.1.2 | Are purchased stock items verified against a specification before use, including defined acceptance criteria? | | |
| | Goods Intake | | |
| 9.2.1 | Are purchase orders, delivery notes, and delivered goods matched during receipt? | | |
| 9.2.2 | Are stock items checked against acceptance criteria/specification prior to release, with additional checks for transport conditions if needed? | | |
| 9.2.3 | Are raw/packaging materials with potential defects held until a decision is made on their disposition? | | |
| 9.2.4 | Are raw/packaging materials clearly identified according to status (e.g., released, hold, quarantined, rejected)? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|-------------|--|-----------------------|-------------------|
| | If a digital system is used instead of physical labelling, does it provide equal assurance of status control? | | |
| | Traceability Identification | | |
| 9.3.1 | Are containers of raw/packaging materials clearly labelled with material identity and batch information? | | |
| | Release | | |
| 9.4.1 | Is there a documented system in place ensuring only released stock items are used in production? | | |
| 9.4.2 | Are releases of materials performed only by authorised Technical Compliance personnel or designated deputies? | | |
| | Water used as a stock item | | |
| 9.5.1 | If water is produced on-site, are documented controls in place to verify potable quality via testing or parameter monitoring with recorded criteria? | Document Ref: | |
| 9.5.2 | Is water treatment equipment designed to avoid stagnation, allow sanitisation, and prevent contamination? | | |
| 9.5.3 | Are materials used in water treatment systems selected to ensure they do not compromise water quality? | | |
| 9.5.4 | If water is purchased, is it treated in line with raw material purchasing requirements as outlined in the standard? | | |
| 10.0 | PRODUCTION | | |
| | General | | |
| 10.1.1 | Is there a documented procedure defining controls for bulk manufacture, filling, and packing operations? | Procedure Ref: | |
| 10.1.2 | Are measures in place at each manufacturing and packaging stage to ensure final product meets acceptance criteria? | | |
| | BULK MANUFACTURING OPERATIONS | | |
| | Essential documentation availability | | |
| 10.2.1.1 | Is relevant documentation available at each stage of manufacturing? | | |
| 10.2.1.2 | Does manufacturing follow defined documentation including: - formula, - raw material list with traceability, - equipment traceability, - detailed methods/specs? | | |
| | Pre-Start clearance checks | | |
| 10.2.2.1 | Are records maintained to show pre-start checks include: - docs & materials available and released, | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|----------|---|----------|-------------------|
| | - equipment clean & functional, - area clear of unrelated materials? | | |
| | Traceability identification | | |
| 10.2.3.1 | Is a traceability code assigned to each batch of bulk product and linkable to final product batch if different? | | |
| | Identification of In-process operations | | |
| 10.2.4.1 | Are all raw materials properly weighed, identified, and traceable with tolerances defined? | | |
| 10.2.4.2 | Can major equipment and containers of raw or bulk product be identified at all times? | | |
| 10.2.4.3 | Are containers of bulk labelled with: - name/code, - traceability code, - storage conditions (if applicable)? | | |
| | In-process controls | | |
| 10.2.5.1 | Are in-process controls and acceptance criteria defined in a specification? | | |
| 10.2.5.2 | Are in-process controls performed to a defined programme and frequency? | | |
| 10.2.5.3 | Are out-of-spec results reported and appropriately investigated? | | |
| | Re-stocking | | |
| 10.2.6.1 | Are unused raw materials re-stocked only if acceptable, in closed, properly identified containers? | | |
| | FILLING & PACKING OPERATIONS | | |
| | Essential documentation availability | | |
| 10.3.1.1 | Is relevant documentation available at each stage of packaging? | | |
| 10.3.1.2 | Does documentation include: - equipment traceability, - list of packaging materials, - detailed specs (filling, closing, coding)? | | |
| | Pre-start clearance checks | | |
| 10.3.2.1 | Are records maintained showing: - all documentation & materials released and available, - clean/functional equipment, - correct coding and clear area? | | |
| | Traceability identification | | |
| 10.3.3.1 | Is a traceability code assigned to each finished unit and traceable to production records? | | |
| | Packaging Line Identification | | |
| 10.3.4.1 | Is the packaging line, product, and traceability code identifiable at all times? | | |
| 10.3.4.2 | Are on-line control equipment checks performed to a defined programme and documented? | | |
| | In-process control | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|-------------|--|-----------------------|-------------------|
| 10.3.5.1 | Are packaging in-process controls and acceptance criteria defined in a specification? | | |
| 10.3.5.2 | Are in-process controls performed to a defined programme and frequency? | | |
| 10.3.5.3 | Are out-of-spec results reported and appropriately investigated? | | |
| | Re-stocking | | |
| 10.3.6.1 | Are unused packaging materials re-stocked only if acceptable, in closed and properly identified containers? | | |
| | Identification and handling of work-in-progress | | |
| 10.3.7.1 | Where filling/labelling is not continuous, are segregation and identification controls in place to prevent mislabelling? | | |
| 10.3.7.2 | Are packaging lines sufficiently separated to prevent mix-ups and ensure line clearance integrity? | | |
| 11.0 | STORAGE AND DESPATCH | | |
| | General | | |
| 11.1.1 | Is there a documented procedure covering stock item storage, release, dispatch, and returns? | Procedure Ref: | |
| 11.1.2 | Do finished products meet defined acceptance criteria before dispatch? | | |
| 11.1.3 | Are storage, shipment, and return activities managed to protect the quality of stock items? | | |
| | Stock item Storage | | |
| 11.2.1 | Are all stock items (bulk and finished) stored under conditions suitable to maintain safety and quality? | | |
| 11.2.2 | Is maximum storage duration (shelf life) defined and documented for raw, packaging, bulk, and finished goods? | | |
| 11.2.3 | Where applicable, are storage conditions monitored to ensure ongoing suitability? | | |
| 11.2.4 | Are items stored/handled according to their risk (e.g., allergens, COSHH, special claims)? | | |
| 11.2.5 | Are stock item containers properly closed/sealed? | | |
| 11.2.6 | Are easily damaged containers (e.g., cardboard) stored off the floor to avoid contamination? | | |
| 11.2.7 | Are quarantined/rejected items stored in controlled, defined locations or using equivalent digital systems? | | |
| 11.2.8 | Do container labels (or digital equivalents) show: - name/code, - traceability code, - storage conditions, - quantity/unit/date if needed? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|-------------|--|-------------------------|-------------------|
| 11.2.9 | Is stock turnover controlled (e.g., FEFO) unless exceptions are justified? | | |
| 11.2.10 | Are periodic inventory checks conducted to confirm: - accuracy, - compliance with acceptance criteria, - and are discrepancies investigated? | | |
| | Re-Evaluation & Shelf life | | |
| 11.3.1 | Is there a documented procedure defining controls for shelf life and re-evaluation of stock items? | Procedure Ref: | |
| 11.3.2 | Is there a system for re-evaluating stored materials before use, preventing use of expired items, and maintaining records of assessments? | | |
| | Positive release | | |
| 11.4.1 | Are finished products verified and tested before release using established test methods and acceptance criteria? | | |
| 11.4.2 | Is product release (including WIP and finished) conducted only by Technical Compliance or their authorised deputies? | | |
| | Despatch & Shipment | | |
| 11.5.1 | Are controls in place during despatch, including: - availability of documentation, - vehicle inspections prior to loading? | | |
| 11.5.2 | Are precautions taken to maintain product quality during transport, where appropriate? | | |
| | Returns | | |
| 11.6.1 | Are returned items clearly identified and stored in defined areas? | | |
| 11.6.2 | Are returned items re-evaluated using established criteria, and only released after passing re-evaluation to avoid inadvertent redistribution? | | |
| 12.0 | INSPECTIONS AND ACCEPTANCE | | |
| | General | | |
| 12.1.1 | Are controls in place at each operational stage to ensure stock items meet quality criteria before use or shipment? | | |
| | Test Methods | | |
| 12.2.1 | Are inspection activities performed using established test methods aligned with acceptance criteria? | | |
| 12.2.2 | Are test methods documented to support training, consistent results, and method validation? | Document Ref(s): | |
| | Acceptance Criteria | | |
| 12.3.1 | Are acceptance criteria (parameter limits) clearly defined for all stock items? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|-------------|---|-----------------------|-------------------|
| 12.3.2 | Are all results recorded, reviewed, and assigned a status such as approved, rejected, quarantined, pending, or disposed of? | | |
| 12.3.3 | Are out-of-acceptance results reviewed by authorised personnel and fully investigated, with supporting re-test records where applicable? | | |
| 12.3.4 | Are final decisions on non-conforming product disposition (e.g., approve, reject, concession) made by authorised personnel? | | |
| | Analytical Materials | | |
| 12.4.1 | Are analytical materials (e.g., reagents, media) labelled with: - Name, strength, expiry date - Preparer's ID - Open date - Storage conditions? | | |
| 12.4.2 | Are in-house prepared analytical materials made using documented procedures, with supporting training records? | | |
| | Sampling | | |
| 12.5.1 | Is sampling carried out only by authorised personnel? | | |
| 12.5.2 | Is the sampling process clearly defined, including: - Method, equipment, location, quantity - Contamination prevention - ID & frequency? | | |
| 12.5.3 | Are samples clearly identifiable to prevent mix-ups (e.g., by code, date, origin, container, sampling point)? | | |
| | Retain Sample | | |
| 12.6.1 | Are identifiable and traceable finished product samples retained under defined conditions and locations, when appropriate or required? | | |
| 12.6.2 | Are identifiable and traceable bulk product samples retained in appropriate containers and storage conditions for a defined period? | | |
| 12.6.3 | Is sample size sufficient to support testing in line with regulatory requirements? | | |
| 13.0 | DESIGN AND DEVELOPMENT | | |
| | DESIGN AND DEVELOPMENT | | |
| | General | | |
| 13.1.1.1 | Is there a documented procedure in place for product design and development? | Procedure Ref: | |
| 13.1.1.2 | Are all finished products developed under this procedure and checked for regulatory and quality compliance? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|------------|--|----------|-------------------|
| | Brief | | |
| 13.1.2.1 | Is a product design brief created including region of sale, legal inputs, customer needs, controls, verification methods, and outputs? | | |
| | Raw Materials | | |
| 13.1.3.1 | Are raw materials assessed for suitability, legal compliance, and fraud risk, with documented evidence (e.g., GM, allergens, banned substances, etc.)? | | |
| | Recipe | | |
| 13.1.4.1 | Are detailed formulation records maintained for all raw materials and their concentrations? | | |
| 13.1.4.2 | Are recipe changes justified and documented for traceability and compliance? | | |
| | Methodology | | |
| 13.1.5.1 | Are manufacturing methods documented to ensure consistent batch production (e.g., temps, times, additions)? | | |
| 13.1.5.2 | Are process parameters and controls clearly recorded to ensure repeatability and compliance? | | |
| | Stability | | |
| 13.1.6.1 | Is stability testing conducted to verify product shelf life? | | |
| 13.1.6.2 | Are stability results reviewed periodically and retained as documented evidence? | | |
| | Compatibility | | |
| 13.1.7.1 | Is compatibility testing between packaging and ingredients conducted to confirm no adverse reactions? | | |
| 13.1.7.2 | Are test findings recorded and corrective actions taken where necessary? | | |
| | Preservative | | |
| 13.1.8.1 | Is preservative efficacy verified via microbiological testing, and compliant with regulations? | | |
| 13.1.8.2 | Are preservation methods validated and included in manufacturing methods as critical controls? | | |
| | Release | | |
| 13.1.9.1–6 | Is a CPSR completed by a qualified assessor before market release, with registration to CPNP and all approvals and documentation retained? | | |
| | LABELLING | | |
| | General | | |
| 13.2.1.1 | Is full INCI-compliant ingredient disclosure present on labels? | | |
| 13.2.1.2 | Are allergens clearly indicated per legal requirements? | | |
| 13.2.2.1 | Has a legally responsible person been designated for product compliance oversight? | | |

| Clause | Checklist Item | Evidence | Compliance Status |
|-------------|--|----------|-------------------|
| 13.2.2.2 | Are the responsible person’s contact details listed on product labels? | | |
| 13.2.3.1–2 | Is there a unique batch code system for each product with traceable batch records for recall? | | |
| 13.2.4.1–2 | Has stability testing determined shelf life, and is the PAO symbol used if required? | | |
| 13.2.5.1 | Is the best before date indicated clearly when required? | | |
| 13.2.6.1–2 | Is the intended product function and safe use instructions included in consumer-friendly language? | | |
| 13.2.7.1 | Are net volume or weight declared in line with metrology requirements? | | |
| 13.2.8.1–2 | Are all required warnings and hazard statements present and compliant with classification regulations? | | |
| 13.2.9.1–2 | Are cruelty-free claims backed by certification and compliant with testing bans? | | |
| 13.2.10.1 | Are organic certification claims verified and documented? | | |
| 13.2.11.1 | Are dermatological claims supported by clinical test reports? | | |
| 13.2.12.1–2 | Are recycling instructions and environmental label compliance present? | | |
| | Legality of Claims | | |
| 13.3.1 | Are product claims: - Non-misleading, - Legally compliant, - Supported by correct ingredient calculations, - Scientifically supported? | | |