# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to describe the process for conducting of internal audits to assess the effective implementation of cosmetic Good Manufacturing Practices and where necessary propose and implement corrective actions.

**2. SCOPE:**

The scope of this SOP applies the applies to the conducting of Good Manufacturing Practices internal audits.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 16: Internal audit.
* Food Safety Management: Requirements for a Food Safety System based on Prerequisite Programmes and Hazard Analysis and Critical Control Point (HACCP) principles

# **5. AUTHORITY AND RESPONSIBILITY:**

Management ensures that Good Manufacturing Practices internal audits are periodically conducted.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Audit team**

Internal audits are carried out by personnel independent of the activity being audited. Internal Auditors need to be trained before being assigned for internal audits.

**6.1 Planning of internal audits**

When planning the internal audits, consideration is given to the status and importance of the processes and areas to be audited, changes affecting the organization, as well as the results of the previous audits. Internal audits are conducted at twice a year as per (GMP SOP015- Form 01 Annual Internal Audit Calendar).

The audit criteria should be in line with the ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices, Food Safety Management: Requirements for a Food Safety System based on Prerequisite Programmes and Hazard Analysis and Critical Control Point (HACCP) principles.

The organisation’s own requirements will also form part of the audit criteria.

An Annual Internal Audit Calendar should be maintained. The calendar may be revised after each audit on the basis of the audit findings.

**6.2 Audit process**

Audits are carried out against audit criteria other relevant standards. Non-conformance reporting is based on objective evidence.

When an actual/potential non-conformance is observed during an audit, both auditee and auditor must agree on the following:

* Objective evidence
* Nature of observed deviation (Major/Minor)
* Corrective / preventive actions and due date, and
* Need for follow-up audits or verification and the due date.

**6.3 Recording the Results of quality audits**

Auditors record the observed non-conformities, deficiencies, and improvement opportunities in the area / department being audited on the GMP SOP015- Form 02 Internal Audit Findings Notification. A formal audit report is compiled within 5 working days after completion of the internal audit.

**6.4 Follow up audits**

When a non-conformance detected during audits is not addressed during the audit, follow up audits shall be conducted. Responsible personnel shall be assigned to keep track of open audit findings and ensure that these are closed within the agreed time frame.

**6.5 Closing of auditing findings**

Once the corrective actions are completed and if further follow-up audit is not required, the audit findings can closed.

The internal audit summary in the is also discussed in the subsequent management review meetings.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title / ID** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Annual Internal Audit Calendar (SOP015- Form 01 Annual Internal Audit Calendar) | English, Text | Electronic | 1 year  | Quality Control (QC) Manager |
| 2 | Internal Audit Findings Notification (GMP SOP015- Form 2) | English, Text | Electronic | 1 year  | QC Manager |
| 3 | Audit Report | English, Text | Electronic | 1 year | QC Manager |

# **8. DOCUMENT AMENDMENT HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Summary of changes from previous version of the document** | **Changes Requested By** | **Remarks**  |
| 0 | First version released for implementation. | N/A | Nil |
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