# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure that there is a system for the creation, approval, control and revision of Quality Management System documentation.

**2. SCOPE:**

The scope of this SOP applies documented information of internal and external origin required Good Manufacturing Practices (GMP) guidelines.

**3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 17: Documentation
* 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 relevant documentation is available, updated and made available as required by Good Manufacturing Practices (GMP) guidelines and Hazard Analysis and Critical Control Point (HACCP) principles.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Creating and updating documented information**

The creation and revision of quality documents, their distribution is controlled through a master list of documents control system. New documents and revisions are reviewed and approved prior to issue and are identified with respect to their revision status.

Appropriate documents are available at locations where they are used. Obsolete documents are identified as such to prevent their unintended use.

# **6.2 Control of documented information**

The required documented information is controlled to ensure that;

1. it is available and suitable for use, where and when it is needed, and
2. it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization addresses the following activities, as applicable:

1. distribution, access, retrieval and use
2. storage and preservation, including preservation of legibility
3. control of changes (e.g. version control), and
4. retention and disposition.

**6.3 Control of documents of internal and external origin**

A (GMP-SOP016-Form 01 Master List of QMS Documents and Records) is maintained that controlled by them.

In case of documents, this master list contains the document identification, Title, Author, Reviewer & Approver, Issuer, Format (e.g. language), Medium (e.g. paper, electronic), Version, Effective Date, and the List of recipients of controlled copies.

In case of records, this master list contains the record identification, Title, Format (e.g. language), Medium (e.g. paper, electronic), Custodian, and Minimum Retention Period.

**6.4 Request for addition or modification**

Employees are encouraged to propose new documents, procedures, forms as and when changes are needed. A document addition or modification request is completed by use of the (GMP-SOP016-Form 02 Document Addition / Change Request).

If the request is approved by the responsible person, the document is prepared . modified, reviewed , approved and distributed. Prior to release, documents are reviewed for adequacy and correctness.

The latest version number and effective implementation date of the amended documented is captured on the master list of documents and records.

**6.5 Identification and revisions**

Changes to documents are reviewed and approved by the same function that approved the initial document. All controlled documents are identified with a unique title, and with respect to their revision level by a revision number. Initial release is code “0”, the next release is “01”, and so on.

**6.6 Document withdrawal**

In case of withdrawal of an existing document that has become obsolete, a (GMP-SOP016-Form 3 Document Withdrawal Notice) is sent to the concerned personnel or function requesting them to remove those documents from their use and destroy them.

Obsolete documents and records may be retained for legal/reference purpose are marked as ‘OBSOLETE’.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title**  | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Master List of QMS Documents and Records (GMP-SOP016-Form 01) | English, Text | Electronic |  |  |
| 2 | Document Addition / Change Request (GMP-SOP016-Form 02) |  |  |  |  |
| 3 | Document Withdrawal Notice (GMP-SOP016-Form 3) |  |  |  |  |

# **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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