# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure changes affecting the quality management system are reviewed, approved, and documented.

**2. SCOPE:**

The scope of this SOP applies to change controls related to but not limited to regulatory analytical methods and specifications, SOPs, Product formulae, manufacturing instructions, cleaning procedures, and equipment.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 15: Change control.
* 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 any changes affecting the quality management system is reviewed and appropriate correction action implemented.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Initiation of Change**

Any employee may request a change. When a change to a quality system is required, the requester will complete a GMP SOP014- Form 01 Managing of Change Request.

A change number consisting of the Department name and a chronological number assigned and tracked by each Department head will be assigned to the request.

Original of the change Request form will be sent to the QC Manager for approval. Once it is approved, original will be held by QC Department and copy of the form will be sent to the requested department for filing.

**6.2 Implementation of Actions**

When an approved change is completed, a notification form will be sent to the Quality Control.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Managing of Change Request (GMP SOP014- Form 01) | English, Text | Electronic | 1 year | Quality Control (QC)  Manager |

# **8. DOCUMENT AMENDMENT HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Summary of changes from previous version of the document** | **Changes Requested By** | **Remarks** |
| V-001 | First version released for implementation. | N/A | Nil |
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