# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure that equipment is suitable for the production of the products, easily cleaned, sanitized and maintained.

**2. SCOPE:**

The scope of this SOP applies to the cleaning and maintaining of equipment used for production of the products.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 5: Equipment
* 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 proper maintenance of facilities and equipment is done to ensure they are reliable and available during and after production.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**Equipment design and installation**

Equipment used are placed in a suitable layout to enable the production of the product, ease of cleaning and proper drainage, movement of materials, mobile equipment and personnel.

Equipment used in the production and readily identifiable by appropriate labelling.

**Maintenance of equipment**

A Master List of Equipment Requiring Maintenance (GMP Form- SOP04-01) is are maintained such that routine repairs and maintenance work is conducted.

Routine maintenance such as lubricating of parts, changing of parts is conducted by qualified and competent personnel whether internally or externally. External maintenance service providers will be sourced from the approved list of external service providers.

**Breakdown maintenance**

When a breakdown maintenance of the equipment is carried out, a Maintenance Log (GMP Form- SOP02) is completed appropriately by the maintenance technician.

**Calibration of measuring instruments**

Laboratory and production measuring instruments used are regularly calibrated. In case the results of calibration are out-of-acceptance criteria, measuring instruments are appropriately identified and removed from service. A Calibration Status of Instrument/Equipment (GMP Form- SOP04-03) is maintained.

An out-of-calibration condition is investigated to determine if there is any impact to the quality of the product and appropriate steps taken based on this investigation.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Master List of Equipment Requiring Maintenance (GMP Form- SOP04-01) | English, Text | Electronic |  | Production Controller |
| 2 | Maintenance Log (GMP Form- SOP02) | English, Text | Electronic | 1 year | Production Controller |
| 3 | Calibration Status of Instrument/Equipment (GMP Form- SOP04-03) | English, Text | Electronic | 1 year | Production Controller |

# **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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