# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure that premises for manufacturing are suitably located, appropriately designed, constructed and regularly maintained and ensure;

a) Protection of the product;

b) To permit efficient cleaning, if necessary, sanitizing and maintenance;

c) To minimise the risk of mix-up of products, raw materials and packaging materials.

**2. SCOPE:**

The scope of this SOP applies to the design, construction and maintenance of production facilities.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 3.5: Personnel Hygiene and Health.
* 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 regular hygiene inspections are conduct for all personnel accessing storage and production areas.

**Employees**

All production employees and visitors are responsible to adhering to this SOP.

# **6. METHOD:**

Premises for manufacturing are suitably located, designed, constructed and maintained.

The following measures are taken into consideration to ensure the protection of the product, permit efficient cleaning, sanitising and maintenance as well as minimise the risk of mix-up of products, raw materials and packaging materials;

**Flow of materials, products and personnel**

Dedicated areas are provided and maintained for the receipt of raw materials, products and access control by personnel is in place to prevent mix-ups. This includes demarcated areas for; sampling of materials, incoming goods and quarantine, storage of bulk products, materials and finished products, processing, packaging, quarantine storage before final release of products.

**Floors, walls, ceilings, windows**

Floors, walls, ceilings and windows in production areas are designed, constructed for to enable ease of

cleaning and, if necessary, sanitization and kept clean and in good repair.

Windows are non-opening design where ventilation is adequate. Windows are opened to the outside environment, are properly screened.

**As and when required**, new construction and design of production areas incorporates considerations for proper cleaning and maintenance, smooth surfaces if appropriate and these surfaces should allow for resistance to corrosive cleaning and sanitizing agents.

**Washing and toilet facilities**

Adequate, clean, washing and toilet facilities are provided for personnel. The washing and toilet

facilities are identified as such, easily accessible to, production areas. Adequate facilities for showering

and changing clothes are provided when appropriate.

**Lighting in operational areas**

Adequate lighting, that is sufficient for operations, is installed in all areas. Lighting is installed in a manner to ensure containment of any debris from potential breakage so as to protect the product.

A GMP Checklist for premises (SOP 03-01) is used to assess the adequacy of location, construction, design and layout.

**Cleaning and sanitisation**

All equipment are cleaned and where appropriate sanitised before production starts. Equipment used in the handling of material and production is inspected daily before operations begin.

Cleaning and sanitisation is carried out in a manner that does not contaminate the raw material and products whether in-processing or finished products.

Separate cleaning equipment are used for cleaning floors and walls and for equipment cleaning.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title / ID** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | GMP Checklist for premises:  SOP 03-01 | 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** |
| 0 | First version released for implementation. | N/A | Nil |
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