# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure that there is a process for treatment of products that are out of specification.

**2. SCOPE:**

The scope of this SOP applies to the rejected finished and reprocessed products raw materials and packaging materials.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 10: Treatment of product that is out of specification
* 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 finished products, materials that are rejected and reprocessed are identified and controlled to prevent their unintended use or delivery.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Rejected finished products, bulk products, raw materials and packaging materials**

Investigations of rejected product or materials should are performed by personnel authorised to do so.

Rejected finished products and material is controlled by;

1. segregation, containment, rejected
2. informing the customer
3. obtaining authorization for acceptance under concession.

The decision to destroy or to reprocess the products and materials is conducted by the personnel responsible for quality as per the (Disposal of Non-conforming Product-GMP SOP05- Form 02).

Rejected finished products and material is disposed-off as per agreement with the respective suppliers.

**6.2 Reprocessed finished products and bulk products**

If all or part of a batch of finished product or bulk product does not meet the defined acceptance

criteria, a decision to reprocess in order to obtain the defined quality should be approved by personnel

responsible for quality.

The method of reprocessing should be defined and approved.

Controls should be performed on the reprocessed finished products or bulk products.

 Results should be reviewed by authorized personnel in order to verify the conformity of the finished product or bulk product with the acceptance criteria.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title / ID** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 2 | Disposal of Non-conforming Product (GMP SOP05- Form 02) | 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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