# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure that cosmetic products will be of consistent quality appropriate to their intended use.

**2. SCOPE:**

The scope of this SOP applies to all quality control laboratory activities.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 9: Quality Control Laboratory
* 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 quality control laboratory activities are performed in accordance to approved specifications, sub-contracted to an accredited external laboratory.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Test methods**

Quality control laboratories should use all test methods necessary to confirm that the product complies with acceptance criteria.

Controls should be performed on the basis of defined, appropriate and available test methods.

**6.2 Acceptance criteria**

Acceptance criteria should be established to specify the requirements to be met for raw materials, packaging materials, bulk products and finished products.

**6.3 Results**

All results should be reviewed. After this review, a decision should be made, notably in terms of approval, rejection or pending.

**6.4 Out-of-specification results**

Out-of-specification results should be reviewed by authorized personnel and properly investigated.

There should be sufficient justification for any re-testing to be performed.

After the investigation, a decision by authorized personnel should be made, notably in terms of deviation, rejection or pending.

**6.5 Reagents, solutions, reference standards, culture media**

Reagents, solutions, reference standards, culture media, etc. should be identified by the following information:

a) the name;

b) its strength or concentration, when appropriate;

c) expiration date, when appropriate;

d) the name and/or signature of the person who prepared it, when appropriate;

e) opening date;

f) storage conditions, when appropriate.

**6.6 Sampling**

Sampling should be performed by authorized personnel.

Sampling should be defined in terms of:

a) sampling method;

b) equipment to be used;

c) amounts to be taken;

d) any precautions to be observed to avoid contamination or deterioration;

e) identification of sample;

f) frequency.

Samples should be identified by:

a) the name or identifying code;

b) the batch number;

c) the date of sampling;

d) the container from which the sample was taken;

e) the sampling point, if applicable.

**6.7 Retain sample**

Samples of finished product should be retained in an appropriate manner and in designated areas. Sample size of finished products should allow analyses to be carried out in accordance with local regulations.

Retain samples of finished product should be kept in their primary package for an appropriate time

under the recommended storage conditions.

Samples of raw materials may be retained according to company practice or in accordance with local regulations.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | Acceptance criteria for raw materials, packaging materials, bulk products and finished products. | English, Text | Electronic | 3 years | Production Controller |
| 2 | Out-of-specification results | English, Text | Electronic | 1 year  | Production Controller |
| 3 | Batch Manufacturing Record | English, Text | Electronic | 1 year | Production Controller |
| 4 | Product Formula | English, Text | Electronic | 3 years | 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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