# **1. PURPOSE:**

The purpose of this Standard Operating Procedure (SOP) is to ensure product complaints and recall are identified, managed and timeously attended to.

**2. SCOPE:**

The scope of this SOP applies to the handling of product complaints and recall.

# **3. DEFINITIONS:**

NIL

# **4. REFERENCES:**

* ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices- Clause 14: Complaints and recalls.
* 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 product complaints and recalls are follow-up, investigated and corrective action implemented as required.

**Employees**

All employees are responsible to adhering to this SOP.

# **6. METHOD:**

**6.1 Product complaints**

**Receipt and Processing of Complaints**

The Quality Control Manager maintains a chronological file of all complaints received from all sources through all channels and all follow-up documentation that is generated as a result of the complaint.

All complaints received will be recorded on the GMP SOP013-Form 1 Customer Complaint Form and processed according to this SOP.

The written records are kept for at least one (1) year after the expiration date of the product, or one (1) year after the date the complaint was received, whichever is longer.

Any complaint involving the possible failure of a cosmetic product to meet any of its specifications shall be reviewed by Quality Control to determine the need for an investigation.

In the absence of the Quality Control Manager the following designated alternates, in order is responsible to receive any complaint calls:

1. Production Manager
2. Administrative Manager

All written and oral complaints regarding a cosmetic product are received, evaluated, investigated and responded to as quickly as possible.

The designated individual receiving the complaint will initiate the Customer Complaint Form (Exhibit 1) and will obtain all information pertinent to the complaint. The written record of each complaint shall contain:

1. The completed Customer Complaint Form
2. All correspondence (letter / fax / e-mail)
3. Investigation Report

Investigate each complaint via referral to and discussion with all concerned departments and records (Production, and QC) arranging for confirmatory laboratory and other checks where indicated. Specifically,

Examine the batch record for the lot in question, with particular interest directed towards those portions of the manufacturing procedure that would impact on the reported deficiency.

Interview those personnel who were directly involved in the manufacture of the product/lot.

Examine several batch records for the same product/potency which were manufactured before and after the lot in question to determine if there were similar deficiencies noted.

Examine the Complaint File to determine if there have been complaints of a similar nature for the product.

Examine retain samples of the product lot to determine, upon visual examination, if there appears to be a problem with the product.

As appropriate to the nature of the complaint, perform all testing of the retain sample to determine if the product/lot specifications are within acceptable ranges.

As appropriate, discuss the nature of the complaint directly with the complainant.

Once the complaint is confirmed with a defective product, it is necessary to consider a recall. Recall shall be undertaking in according with the GMP SOP05- Form 02 Disposal of Non-conforming Product.

Summarize the results of the investigation, and record details of disposition of the complaint in the Customer Complaint Form, together with all other pertinent documentation.

Periodically, review the Complaint File and identify complaint trends which may signal a basic product problem.

On a monthly basis, forward a summary of all complaints received to the General Manager, Production Manager, and Marketing Manager, which includes the following items:

* Complaint No.
* Identity of Complainant
* Nature of Complaint
* Product name
* Lot No.
* Quantity involved
* Status/Summary of Investigation
* Final Disposition
* Document Reference No. (for responding of the product complaint in writing)

A GMP SOP013-Form 2 Complaint Summary Report is maintained and will be the first page in the Complaint File, and will serve both as a Table of Contents, and as a means to quickly and easily see trends which may be occurring with particular products or product lots.

**6.2 Product recalls**

Product recalls will be identified timeously either from the customer complaints or during the process of finished products.

Only authorised personnel should coordinate the recall product recalls process. Product recall operations should be capable of being initiated promptly and in a timely manner.

The appropriate authorities should be notified of recalls which could have an impact upon consumer

safety. Recalled products should be identified and stored separately in a secure area while awaiting a

decision.

The product recall process should be periodically evaluated.

# **7. RECORDS:**

The following records are maintained.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **Record Title** | **Format** | **Medium** | **Retention Period** | **Custodian(s)** |
| 1 | GMP SOP013-Form 1 Customer Complaint Form | English, Text | Electronic | 1 year | Quality Control (QC)  Manager |
| 2 | GMP SOP013-Form 2 Complaint Summary Report | English, Text | Electronic | 1 year | QC Manager |
| 3 | GMP SOP05- Form 02 Disposal of Non-conforming Product | English, Text | Electronic | 1 year | 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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