| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Quality Assurance | **SOP No.:** |
| **Title:** Handling of Customer Complaint | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
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## 1.0 OBJECTIVE:

To lay down a procedure for handling of customer complaint.

## 2.0 SCOPE:

This procedure is applicable to handling of product complaints received from the marketing department/direct from various customers.

## 3.0 RESPONSIBILITY:

Executive and Manager of Production, Engineering, Formulation & Development, Quality Control, Medical and Quality Assurance departments for investigation of the complaint.

Manager-Quality Assurance for handling the market complaint and communication with the complaint

## 4.0 DEFINITION(S):

NA

## 5.0 PROCEDURE:

5.1 Any communication oral or written received from any customer, retailer, distributor or marketing department on deficiency of product related to purity, efficacy or packaging defect shall be considered as a market complaint. A shall be responsible for allotting the batch numbering pattern for a new product before the start of production.

5.2 Manager, QA shall be responsible for the handling of complaint. He shall be assisted by a technical team from Quality Assurance, Engineering, Production (Manufacturing and Packaging), Formulations & Development, Quality Control and Medical department, depending on the nature of the complaint.

5.3 On receipt of the complaint, the details shall be recorded in the “Customer Complaint Register” (Refer Annexure – I).

5.4 Each complaint shall be assigned a unique 18 digit sequential number.

- The first three digits “DCP” stands for Decoding Pharma”.

- The 4th digit is a "slash"
- The 5th – 7th digits "QAD" stands for Quality Assurance Department
- The 8th digit is a "slash"
- The next three digits "CCC" stands for Customer Complaint Communication.
- The 12th digit is a "slash"
- The 13th – 15th digit indicate the serial number of the complaint which starts with the number "001"
- The 16th digit is a "slash"
- The last two digits "22" stands for the year 2022

Example:

The first complaint for the year 2022 will have serial number reference DCP/QAD/CCC/001/22.

5.5 The investigation team shall initiate the investigation by filling the "Customer Complaint Investigation Report" (Refer Annexure–II) and identify the complaint for packaging defect, product quality or adverse drug reaction.

5.6 The Manager-QA shall acknowledge the receipt of the complaint directly through writing to the complaint within three working days. Manager-QA shall also request for the complaint sample from the complaint if not provided with the complaint. This shall be required for quality related complaints to study the nature of complaint and comparison with control sample.

5.7 In case, all details are not received within 30 days from the date of receipt of the complaint, the complaint shall be treated as closed with necessary intimation to the complaint.

5.8 On receipt of the complaint sample, it shall be checked for counterfeit. Incase found counterfeit, inform to regulatory authority.

5.9 QA Manager shall thoroughly examined for integrity of pack, physical appearance, any signs of tampering etc. The necessary details shall be recorded and signed by Manager-QA.

5.10 Manager-Quality Assurance shall initiate the investigation through review of all related batch documents, complaint sample, control sample, etc to identify the exact nature of the problem. Subsequently Production / Formulations & Development / Medical department shall be referred for the investigation.

5.11 The control samples of the batch shall also be examined with respect to the complaint received.

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5.12 The complaint product shall be subjected to analysis relevant to the nature of the complaint. In case of complaints related to adverse reaction, the relevant biological tests shall be carried out.

5.13 Depending on the severity of the complaint, intense investigation shall be carried out through checking of batch records, quality control analytical records, distribution records, material sources, deviation in batch process, if any in consultation with the related departments.

5.14 After completion of the investigation a detailed report shall be prepared by the investigating team with recommendation to avoid recurrences.

5.15 The batch history shall also be checked for any reporting of similar complaints in the batch with details and reference number, if applicable.

5.16 In case of quality related complaints, QA and F & D shall suggest the solution after identifying the problem.

5.17 If a product quality defect is identified or suspected in the complaint batch, previous and succeeding batches shall be checked to determine whether they are also affected. Where the active pharmaceutical ingredient of the same batch or lot has been used in other batches of the product, batches having the active ingredient may be required to be tested based on recommendation of investigating team.

5.18 The “Customer Complaint Investigation Report” (CCIR) Refer Annexure–II) shall be completed along with all observations and recommendations and the completed report shall be forwarded to the complaint. If necessary, the report can be accompanied with the additional details.

5.19 In case the complaint batch fails to meet the predetermined approved specifications, it must be recalled from the market as per SOP.

5.20 The detailed findings of the investigation shall be communicated to the complaint and a copy of the communication shall be attached with the CCIR.

5.21 Necessary entries shall be made in the ‘‘Customer Complaint Register’’ and the complaint shall be closed.

5.22 If the further queries raised by the complaint, the investigation shall be continued till it closed.

5.23 Complaint records shall be reviewed regularly for any indication of specific problem

and recurring problems that require attention.

5.24 The competent authorities shall be informed if the action for a possible faulty manufacturing, product deterioration or any other serious quality problem with the product is observed.

**Note: The copy of the market complaint communication and its investigation report shall be attached with that relevant Batch record.**

## 6.0 ABBREVIATION(S):

CCIR : Customer Complaint Investigation Report

SOP : Standard Operating Procedure

QA : Quality Assurance

F & D : Formulation & Development

## 7.0 REFERENCE(S):

NA

## 8.0 ANNEXURE(S):

Annexure-I: Customer Complaint Register

Annexure-II: Customer Complaint Investigation Report

## 9.0 REVISION CARD:

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION |
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