STANDARD OPERATING PROCEDURE		
Title **HANDLING OF COMPLAINTS**		
SOP No.: *XXX*	**Revision No.:** **001**	**Effective Date** *DD-MMM-YYYY*

1.0 Purpose

1.1 This Standard Operating Procedure (SOP) describes how complaints received are to be handled.

2.0 Scope

2.1 This SOP applies to complaints received against the company's product and services.

3.0 Responsibility

3.1 All personnel receiving a complaint shall record the complaint on the Complaint Record Form (*FORM-XXX*).

3.2 *Quality Assurance (QA) / Quality Control (QC)* department is responsible for issuing a case number to each complaint, maintaining a Complaint Register (FORM-XXX) and a file designated for complaints.

3.3 QA / QC with the help of other departments shall perform necessary investigation. Head of QA / QC is responsible for reviewing and ensuring that complaints are appropriately handled, investigated and appropriate measures are taken in respect of the defective products and to prevent recurrences.

3.4 *Designated responsible person* shall be responsible for notifying the *National Regulatory Authority* if product recall is to be initiated following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product. A summary of action taken shall also be furnished to the *National Regulatory Authority* and complainant.

4.0 Procedure

4.1 Complaints may be received from internal or external source and as verbal feedback or written feedback. Verbal feedback may be received in person or via a telephone conversation. Written complaints may be received in the form of letters, faxes, e-mails,

etc. Nevertheless, all complaints shall be recorded using the Complaint Record Form (*FORM-XXX*).

4.2 Complaints can be lodged either against the service (e.g. shipment / delivery) or products, nevertheless all complaints should be handled appropriately. Complaints against products manufactured and distributed by the company may include (but not limited to) deficiencies of containers, labels, materials, purity, quality of a distributed product and Adverse Product Reaction, all complaints regarding the products must be reported to the QA / QC immediately. Sometimes customer may also request to return a product, in such instances assessment should be made to determine whether it is due to (or can potentially lead to) product quality issues, the case should be handled as a complaint after proper evaluation.

4.3 QA / QC upon notification of a complaint, will document the complaint on a Complaint Record Form (*FORM-XXX*) with the information: complaint case number, customer (name, business address and phone number), product, batch number, quantity involved, nature /reasons for complaint. If there is insufficient data, additional information from the originating source should be requested.

4.3 QA / QC (with the help of other departments) shall immediately initiate investigation of the complaint. The investigation shall include review of the existing stock of the same batch and all relevant documents related to the batch of product.

4.4 If a product defect is discovered or suspected in the batch, other batches should also be checked to determine whether they are also affected. In particular, other batches or products that may contain product from the defective batch (e.g. reworked batch) should be investigated.

4.5 If the investigation reveals serious product quality problem and/or product is potentially the cause of adverse reactions, a recall shall be initiated in accordance with SOP on Product Recalls. All *National Regulatory Authorities* (including those where products are exported to) shall be informed in the event that a recall is activated.

4.6 If the investigation reveals a minor defect which will not affect product quality, corrective action should also be proposed to prevent recurrence.

4.7 Investigations should be completed within *XX* days from the date of receiving the complaints.

4.8 The outcome of the investigation, any decision or measure taken as a result of the complaint and the corrective action to prevent recurrence should be recorded in the Complaint Record Form (*FORM-XXX*) and referenced to the corresponding batch records.

4.9 If the complaint involves the exchange / return of goods, all returned goods shall be handled in accordance with SOP on Handling Returned Goods (*SOP-XXX*).

4.10 A register of the complaints (*FORM-XXX*) shall be maintained, it should include the complaint case number, date, product, batch number, brief description of the complaint, the proposed completion date and actual completion date, and remarks (e.g. product recall number).

4.11 All complaints shall be reviewed as part of annual Product Quality Review to determine whether there are specific or recurring problems that may require attention and might justify the recall of marketed products. For recurring problem, a trending shall be established in order to identify the possible systemic defects.

5.0 Reference to other documents

5.1 Complaint Record Form (*FORM-XXX*)
5.2 Complaint Register (*FORM-XXX*)
5.3 SOP on Product Quality Review (*SOP-XXX*)
5.4 SOP on Product Recalls (*SOP-XXX*)
5.5 SOP on Handling Returned Goods (*SOP-XXX*)

6.0 END OF DOCUMENT

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REVISION HISTORY

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