Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-015-03	Effective Date:	
	Supersedes:	QA-015-02	Next Review Date:	
	Department:	Quality Assurance	Page:	1 of 4
TITLE: PRODUCT RECALL				

1.0 PURPOSE:

To provide a procedure for recalling of the product voluntarily based on the conclusions drawn from a complaint, or on observing any quality problem in the product, which is manufactured and released by Discovery Laboratories Pvt. Ltd.

2.0 SCOPE:

The procedure is applicable to the personnel from Production, Quality Control, Quality Assurance, Warehouse, Marketing and Research & Development (R&D) departments involved in the investigation of the complaints received or the quality problems observed and to identify the causes for the incident/rejection and to take necessary corrective and preventive actions, pertaining to the products manufactured and released by Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

It is the responsibility of the Production, Quality Control, Quality Assurance, Warehouse, Marketing and R&D departments to follow the procedures as described in this SOP in product recall activities.

4.0 DEFINITIONS:

4.1 **Recall:**

Calling back of the product from any customer because of the reasons that are susceptible to cause impact on quality of the product.

5.0 PROCEDURE:

5.1 The conditions under which as API dispatched to a customer should be recalled are classified as follows:

5.1.1 If any OOS observed in the retained samples results indicating the deterioration of the product.

5.1.2 By any other means, which states that pertaining batch material has quality problems.

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5.1.3 Stability problem subsequent to the dispatch.

5.1.4 A condition when based on an investigation carried out on receipt of complaint when it has been established that the product fails to meet the specifications.

5.2 On observing the quality problem or on suspicion of the quality of the product, immediately information shall be forwarded to the customer(s) through marketing departments to hold the material and not to precede further operations until the investigation completed. The information sharing with customers should be defined after completion of the investigation.

5.3 Quality Assurance department shall initiate an investigation in co-ordination with Production, QA, QC and R&D if required.

5.4 A thorough investigation shall be done as per the concerned SOPs.

5.5 After conclusion drawn from the investigation a meeting will be arranged by QA and a decision whether to initiate a recall or non-recall (in case if the suspicion clarified) shall be taken collectively.

5.6 QA is the only authority to communicate the decision in either case i.e., a recall or non-recall.

5.7 On making recall decision, the QA department shall intimate to the marketing department to inform the customer regarding the decision immediately.

5.8 QA shall verify distribution records, informs to marketing department with the list of customers to whom the material was supplied to be recalled.

5.9 In case of the product being established to cause serious risk to the consumers then in such case Discovery shall notify the concerned national authorities of the risks involved.

5.10 In case of the material being sent to more than one customer, the marketing department shall ask all the customers to arrange for returning the batch under question.

5.11 The recall shall be completed within 30 working days from the date of recall initiation, if the recall is not completed within the stipulated time, the reasons for not completion shall be recorded and decision will be taken accordingly.

5.12 On receipt of the material back from the customer, QA, Production and Warehouse check the quantities the material shall be quarantined in order that there is no mix-ups with other approved batches.

5.13 The Quality Assurance department shall initiate steps to be taken to handle the returned material as per the SOP 'Handling of returned goods'

5.14 When a conclusion is derived based on further evaluation by the investigation team, steps should be taken either to reprocess or destroy the batches, based on the R&D suggestion.

5.15 The details of the request for return of the batch, receipt at Discovery premises, procedures followed for handling the batch shall be recorded by Quality assurance department.

5.16 Recall reference number should be allotted to each recall as follows:

RC/XXX/YYNNN

Where,

RC - indicate recall

XXX - indicates the product code along with stage code.

YY - indicate last two decimals of current year.

NNN - indicates serial no. of the recall of particular product in the year

e.g.: RC/DAH-II/17001.

6.0 FORMATS / ANNEXURE(S):

6.1 Recall Report : QA015-FM168

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7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.06.2007	New SOP is introduced	--
01	01.07.2009	SOP format changed and reviewed for more clarity.	--
02	15.06.2014	Revised as per current SOP & more clear and clarity.	--
03		1. SOP format changed make to inline with SOP-QA-001-04. 2. Recall report format is introduced. 3. Recall reference numbering system is introduced. 4. Altogether procedure has been rephrased for better clarity.	CCF/GEN/ 17028