Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QA-014-05	Effective Date:	
	Supersedes:	SOP-QA-014-04	Next Review Date:	
	Department:	Quality Assurance	Page:	1 of 6
TITLE: HANDLING OF RETURNED GOODS				

1.0 PURPOSE:

To lay down a procedure for handling, storage, investigation and evaluation of returned goods.

2.0 SCOPE:

This procedure is applicable for handling of returned goods, which are returned from the market at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 Ware House Personnel are responsible to receipt of return goods from customer, store and complete the necessary documentation.

3.2 QA personnel are responsible for inspection of the returned goods material.

3.3 QC personnel are responsible for sampling and testing as per requirement.

3.4 Production personnel are responsible for repacking or reprocessing of returned goods as per outcome of investigation.

3.5 Head-QA / Designee is responsible to take final decision on the returned goods disposition.

4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:

5.1 Products shall be returned from the market for any one/ some of the following reasons but not limited to:

5.1.1 Market complaint from Customer.

5.1.2 Stocks returned from distribution system, due to Date Expired Products, Packing problem, Commercial reasons, recall materials etc.

5.2 The decision for acceptance of returned goods from customer shall be authorized by Head Quality assurance

5.3 Ware house personnel shall check the necessary documents. If found complied, receive the Returned material.

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5.4 Ware house personnel shall fill the "Return goods report (RGR)" as current version of QA014-FM096and Warehouse shall obtain the statuary clearance for the products returned, if any

5.5 Warehouse shall cross verify the returned quantity against dispatched quantity and record the data.

5.6 Warehouse personnel shall strike off (diagonally with pen/ marker) the all approved/ release labels and customer labels, if any present on the containers.

5.7 Warehouse shall clearly identify all returned goods, segregate and quarantine in a secured place (designated areas). Such materials shall be stored in Warehouse control till investigates and determines the final disposition.

5.8 Where facilities are not available within Warehouse area (for reasons of materials requiring storage in controlled or special storage conditions or due to storage constraints) the same shall be maintained in the Rejected room.

5.9 In such cases, an equivalent control shall be exercised by means of adequate segregation, identification and quarantine in a secured place that shall prevent any inadvertent usage before determines the final disposition.

5.10 After received Return Goods report from Ware house, QA In charge shall enter the details "Return Goods Inward Register as per the current format No.QA014-FM097and shall assign the Return goods report number.

5.11 Return Goods Numbering System:

Return Goods Material number system shall be given as RG/XXX/YYNNN.

Where,

RG - Stands for Returned Goods

XXX - Product code with stage

NNN - Stands for the Sequential No. 001, 002…

YY - Stands for the last two digits of the Year

e.g.: RG/DAH-II/19001 indicates first Returned goods received in the Year 2019.

5.12 QA shall cross verify the details filled by Warehouse by verifying the material containers and shall record the comments, if any.

5.13 QA shall check the complaint log, whether the goods were returned following the receipt/ investigation of the complaint.

5.14 In case no complaint is recorded, then QA shall get clarification from customer. In case it is a complaint, proceed as per complaint SOP.

5.15 Return goods shall be proceeded further for investigation.

5.16 **Investigation:**

5.16.1 QA representative shall inspect the returned goods with a view to determine their suitability either for their return to approved stocks or for distribution.

5.16.2 Each delivery of the returned goods and each batch within a delivery of returned goods shall be separately evaluated by QA representative for disposition.

5.16.3 QA representative shall assess the returned goods:

Physical condition of the receipt of the containers

Correctness of identification

Intactness of seals

5.16.4 QA representative shall evaluate each batch for the following obvious defects and goods with the below defects:

Physically damaged primary packs

Visible evidence of deterioration

Evidence of adulteration or tampering

Lacking correct identification

Containers returned without seals.

5.16.5 In addition to the above, the subject product batch shall be subjected to the appropriate chemical and physical testing in order to assess the possible risk of:

Counterfeiting

Physical or chemical degradation of material or product due to improper storage or transit condition

Adulteration

Investigation shall be extended to other batches or products, if the assessment implicates other batches or products.

5.17 Based investigation conclusion and QA recommendations, QC shall carry out the laboratory analysis.

5.18 If the Discovery seals are intact then the test parameters (either complete analysis or partial analysis) to be analyzed for the Returned goods shall be decided by Head-QA / Designee.

5.19 If the containers are sealed by the Customers, complete analysis shall be carried out and the same shall be recommended by QA.

5.20 In case of damaged seal and/or container present then the sampling and testing shall be carried out based on investigation conclusion.

5.21 If the product has reached or exceeded retest due date, then the product shall be subjected to complete analysis as per specification.

5.22 QA shall inform to QC along with “Complete Analytical Test Requisition form” for Particular product & request for collecting sample.

5.23 QC chemist shall sample from each container of the returned material and affix sampled label on the container. The batches shall be allotted with new analytical report number for easy traceability.

5.24 QC shall conduct sampling and testing as per instruction given in the report / recommended by QA.

5.25 The material shall be analyzed as per released specification.

5.26 After completion of analysis, the QC personal shall hand over the complete analytical data to QA for further assessment.

5.27 Based on the inspection and laboratory analysis, QA representative shall finish the investigation and shall provide conclusion to dispose returned goods.

5.28 Only material recommended by QA are suitable for reuse shall be returned to production.

5.29 Product shall be suitably reprocessed/ reworked, after QA assessment and acceptance.

5.30 The maximum time limit, unless and otherwise justified by QA, for completion of closing of RGR shall be 60 working days from the date of initiation of RGR.

5.31 QA representative shall record the details of RGR closing in returned goods log and RGR.

5.32 All applicable documentation shall be maintained by QA.

5.33 QA shall monitor action plan throughout the operations till the returned goods is reused/ reworked/reprocessed or disposed off.

5.34 Return good / Rejected material room lock and key shall be maintained by Quality Assurance.

5.35 The status of returned goods shall be reviewed on annual basis as part of APQR.

6.0 FORMATS / ANNEXURE(S):

6.1 Returned Goods Report : QA014-FM096

6.2 Returned Goods Inward Register : QA014-FM097

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	20.10.2017	1. SOP format changed make to inline with SOP-QA-001-05. 2. Responsibilities are elaborated. 3. Return goods numbering system was modified. 4. Returned goods information form contents have been rephrased for better clarity. 5. Checklist Cum Investigation of Returned Goods form contents has been rephrased for better clarity. 6. Returned Goods inward Register has been rephrased for better clarity. 7. Altogether procedure has been rephrased for better clarity.	CCF/GEN/ 17025
04	25.05.2019	1. Checklist Cum Investigation of Returned Goods form contents has been rephrased for better clarity and name changed as Return goods report and Returned goods information form is removed. 2. The instruction for dispatch of physical characteristics failed material to other customers is removed 3. The instruction for investigation is elaborated with assessment requirement to other batches / products	CCF/GEN/ 19021
05		Return goods / Rejected material lock and key access responsibility has been incorporated.	CCF/GEN/ 21018

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