 Discovery Labs	<b>STANDARD OPERATING PROCEDURE</b>			
	SOP No.:	SOP-QC-043-02	Effective Date:	01.01.2017
	Supersedes :	SOP-QC-043-01	Next Review Date:	31.12.2019
	Department:	Quality Control	Page:	1 of 3
<b>TITLE: CONTROL SAMPLE MANAGEMENT</b>				

## 1.0 PURPOSE:

To lay down a procedure for handling of control samples.

## 2.0 SCOPE:

This procedure is applicable for storage, maintenance and disposal of control sample in Quality control department at Discovery.

## 3.0 RESPONSIBILITY:

- 3.1 Analyst-QC is responsible to follow this SOP.
- 3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.
- 3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.


## 4.0 DEFINITIONS:

NIL

## 5.0 PROCEDURE :

- 5.1 Quality Control department is to maintain the sufficient quantity of control samples for finished products i.e., for two complete analysis as mentioned in the concerned material specification and method of analysis.
- 5.2 The control sample shall be packed in duplicate in double LDPE bags twisted, tied and placed in HDPE/Fiber drums similar to packaging conditions of dispatch batches or in the same packing system in which the Intermediate is stored. Paste the "Control sample" label (QC043-FM021) on the outer packing of each and every batch/consignment.
- 5.3 Retention samples shall be stored product wise secured lock and key control sample room. This room shall be under control of Head-QC/ designee.
- 5.4 Control samples of rejected batch need not be stored.
- 5.5 Where re-sampling is done and the initial sample found to be invalid during the investigation of OOS results, the initial control samples shall be removed and control sample from the re-sampled one shall be kept.

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5.6 Reserve period for all the control samples is one year after the re-test date of the batch or 2 years after distribution of the batch, whichever is the longer.

5.7 Review the control samples for its description once in year (i.e. in the same manufacturing month of every year) and record the details in “Control sample inspection and destruction record”.

Acceptance criteria for inspections: + 1 month from same manufacturing month of every year

#### 5.8 CONTROL SAMPLES ROOM MONITORING:

5.8.1 The control samples room temperature shall be monitored daily afternoon hours. The afternoon recording is considered keeping in the view of highest probable temperature.

5.8.2 The temperature recording can be done either with the help of a calibrated thermometer or hygrometer or with the help of calibrated temperature indicator probe.

5.8.3 QC Analyst / Executive shall record the temperature and humidity of the control sample room daily.

#### 5.9 STORAGE AND HANDLING

5.9.1 Keep all the control samples at room temperature. The products which are not stable at room temperature are to be stored as per their recommended storage conditions.

5.9.2 The control samples can be used for any of the following purposes:

5.9.2.1 To satisfy any regulatory requirement /queries.


5.9.2.2 For additional tests as per customer /regulatory requirements.

5.9.2.3 For investigation of customer complaints /queries (If any).

5.9.2.4 The quantity from sample can be issued for evaluating the sample as working standard if the product campaign is not active.

5.9.3 The quantity used shall be recorded in control samples register (QC043-FM013).

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5.9.4 The entries for reserve / retention / control samples room shall be restricted to authorized personnel only. List of authorized personnel to control sample room is as per annexure-1.

5.9.5 The housekeeping personnel shall be allowed for cleaning purposes under the supervision of an authorized person.

5.9.6 The auditors / customers / regulatory agencies shall be allowed for inspection purposes in presence of authorized personnel.

#### 5.10 Disposal of control samples:

5.10.1 The control samples shall be disposed off / discarded upon expiration of preservation period and the same shall be recorded in the “Control sample register”.

5.10.2 Control samples shall be sent to incinerator / ETP in the presence of responsible QC person.

### 6.0 FORMATS / ANNEXURE(S):

6.1 Control Sample Register : QC043-FM013

6.2 Control Sample : QC043-FM021

6.3 Authorized personnel list for control sample room : Annexure-1

### 7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	12.07.2016	New SOP introduced across all the API manufacturing facilities of discovery.	---
01	01.01.2017	1. SOP revised by changing into format as per SOP for SOP. 2. Control sample register contents were modified. 3. Control sample label contents were modified. 4. Altogether procedure has been rephrased for better clarity.	QC-CRF-025/16

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