TITLE: CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA)

1.0 PURPOSE:

To lay down the procedure for establish the Corrective Action and Preventive Action during Out of Specification results, Deviations, Complaints, Returned goods, Product recall and other investigation.

2.0 SCOPE:

This procedure is applicable to all departments at Discovery Laboratories (P) Ltd.

3.0 RESPONSIBILITY:

3.1 HODs / Designee of respective departments are responsible for below activities ;

- To carry out the investigation to establish the root cause and CAPA.
- To ensure timely execution and review of CAPA in their areas
- Impart training on the revised procedures to the concerned personnel

3.2 Head-QA / Designee

- To verify the established CAPA for appropriateness
- To ensure CAPA follow-up for implementation followed by the closure of the CAPA

4.0 DEFINITIONS:

4.1 **Corrective Action:** Action taken to eliminate the causes of Non-conformities, in order to prevent recurrence.

4.2 **Preventive Action:** Action taken to eliminate the causes of a potential Non-conformities, in order to prevent their occurrence.

5.0 PROCEDURE :

5.1 Corrective Action and Preventive Action shall be concluded based on the investigation.

5.2 Head-QA / Designee shall review and verify the proposed CAPA by the initiating department and decide action required to remedy the situation.

5.3 Corrective Action and Preventive Action shall be established for below circumstances ;

5.3.1 Whenever a material fails to meet the specification (OOS)

5.3.2 Whenever a deviation takes place

5.3.3 Whenever a Complaint received

5.3.4 Whenever a Retuned goods received

5.3.5 Whenever a Product recall received

5.3.6 Any other appropriate action against investigation

5.4 Corrective Action is a term that encompasses the process of product failures, Complaints and other non-conformances. This includes ;

5.4.1 Review and define the failure or non-conformance

5.4.2 Find the cause for failure or non-conformance

5.4.3 Develop an action plan to correct the problem and prevent recurrence

5.4.4 Implement the action plan

5.4.5 Evaluate the effectiveness of the Corrective Action

5.5 Preventive Action is a process for detecting potential failures or potential non-conformances and prevents their occurrence. This includes ;

5.5.1 Identify the failure or non-conformance

5.5.2 Find the cause of the potential failure / non-conformance

5.5.3 Develop a plan to prevent their occurrence

5.5.4 Implement the action plan

5.5.5 Evaluate the actions taken and the effectiveness in preventing the potential failure / non-conformance

5.6 Concern department person shall raise the request to QA for the CAPA form with brief details of failure / non-conformity.

5.7 QA personnel shall issue the Corrective Action and Preventive Action (CAPA) form (QA033-FM004) allotting CAPA number and same shall be logged in the Corrective Action and Preventive Action Record (QA033-FM133).

5.8 As a result of proposed CAPA in the existing system, any change in the Manufacturing process, procedures or documents shall be addressed through Change Control procedure.

5.9 Head – Initiating department / Designee shall be responsible for implementation of proposed CAPA to ensure recommended changes have been completed, appropriate trainings to the concerned personnel and finally fulfillment of CAPA objective.

5.10 Head – QA / Designee shall be responsible for review of effectiveness of proposed CAPA.

5.11 Upon satisfactory implementation of the CAPA by the Initiator department, QA Department shall close the report after verification of the results / effectiveness of the actions.

5.12 CAPA should be closed within 60 days otherwise justified.

5.13 **CAPA Numbering System:**

QA personnel shall assign the number and issue the CAPA form (QA033-FM004) to concern department by assigning the CAPA number as follows;

CAPA/YYNNN

Where

CAPA: Corrective Action and Preventive Action

YY : Represents last two digits of the Calendar Year

NNN : Represents the Serial number starts from 001 for the Calendar Year.

Ex: CAPA/17001, Indicates first CAPA initiated in the year 2017

6.0 FORMATS/ ANNEXURE(S):

6.1 Corrective Action and Preventive Action Record : QA033- FM004

6.2 Corrective Action and Preventive Action (CAPA) Form : QA033-FM133

7.0 CHANGE HISTORY:

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	G. Swapna	Ch. Mahendar Reddy
Department	Quality Assurance	Quality Assurance	Quality Assurance

TITLE: CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA)

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	20.02.2017	The procedure divided from" Deviation-Corrective Action And Preventive Action".	QA-CRF-014/16
01	01.01.2018	SOP format changed make to inline with SOP-QA-01-05	CCF/GEN/ 17037

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