STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Corrective action and Preventive Action (CAPA)	**Effective Date:**
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1.0 OBJECTIVE:

To lay down the Procedure for Corrective and Preventive Action(s) (CAPA).

2.0 SCOPE:

This SOP is applicable for all Corrective and Preventive Action(s) that are recommended and to be documented at …….

3.0 RESPONSIBILITY:

QA (Officer/ Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP. Issuance of CAPA form and to maintain the log.

4.0 ACCOUNTABILITY:

Head QA: Approval, ensure Training and Implementation of this SOP. Approval/Rejection of CAPA.

5.0 DEFINITIONS:

5.1 Non-Conformities: Non-conformities in products, manufacturing process, equipment, building and facilities with respect to predetermined acceptance criteria, specification, or cGMP elements.

5.2 Corrective Actions: The action taken to eliminate the causes of an existing non-conformity, defects or other undesirable situation in order to prevent recurrence, to a degree appropriate to the magnitude of problems and adequate with the risks encountered.

5.3 Preventive Actions: The action taken to eliminate the causes of a potential non-conformity, defects or other undesirable situation in order to prevent occurrence, to a degree appropriate to the magnitude of problems and adequate with the risks encountered.

5.4 CAPAER: It is defined as a review performed after completion of a CAPA activity to evaluate the effectiveness in reducing the potential for future incidents or non- conformance.

6.0 PROCEDURE:

6.1 All the non-conformities occurring in procedures like Handling of Deviations in Facility, Standard Operating Procedures, BMR & BPR, Standard Test procedures/Specifications, Self Inspection, Change

Control; Handling of Market Complaints; Product Recall; Incidents; Annual Product Review; Trend analysis; Handling of Raw material, Packaging material, In-process/Semi-finished and Finished products; consignment received from vendors, etc. shall be addressed through CAPA.

6.2 Initiating department shall raise the request to QA for issuance of Corrective and Preventive Action Form in the Format, Titled **"Request Form for Issuance of Documents"** of SOP, Titled **"Procedure for Documentation & Data Control"**.

6.3 Officer/Executive QA shall assign a CAPA number in **"Corrective Action and Preventive Action Record"** as shown in **Annexure-II** and same number shall be entered in **"Corrective Action and Preventive Action Form"** as shown in **Annexure-I**.

6.4 Assignment of CAPA Number:

CAPA/YY/NNN

Where,

CAPA: Denotes Corrective Action and Preventive Action

/	**:**	separator
YY	**:**	Last two digits of the Calendar Year
/	**:**	separator
NNN	**:**	Serial Number of the CAPA raised in current Calendar Year.

6.5 INVESTIGATION AND CAPA PROPOSAL:

6.5.1 The Initiator of Concerned Department shall write the Description of Non conformities and perform Investigation in consultation with Head of Initiating Department as per SOP, Titled **'Root Cause Analysis'** and if applicable, RCA No. shall be recorded in CAPA Form.

6.5.2 The Concerned Department Head along with QA and other cross functional Department shall thoroughly investigate the root cause of non-conformities related to Facility/Process/Software/ Equipment/Instrument/Documents/System/Utility/Product.

6.5.3 Initiator of Concerned Department shall mention the investigation finding of non-conformance in CAPA which shall be further reviewed by Head of Initiating Department along with sign & date.

6.5.4 Concerned Department shall determine CAPA action plan to eliminate the causes of potential non conformities and / or encountered non-conformities in order to prevent their occurrence and / or recurrence.

6.5.5 Investigation shall be extended to other batches also that may be associated with specific failure or non-conformities and shall enter the detail in CAPA form for investigation findings.

6.5.6 Initiating Department Head shall assign the proposed Corrective Action and Preventive Action against the root cause findings along with sign and date of responsible department and target completion date.

6.6 IMPACT ASSESSMENT OF PROPOSED CAPA :

6.6.1 Manager QA shall further review the proposed CAPA and give comments for Impact assessment related to Proposed CAPA along with sign and date.

6.6.2 Impact assessment of recommended CAPA on other batches, similar existing system, documents, other products, validated processes, on-going stability studies and testing procedures etc. shall be determined by user department in-consultation with CAPA Manager QA and shall be recorded in CAPA Form.

6.7 APPROVAL OF CAPA:

6.7.1 After receiving the review comments from Manager QA, final assessment of CAPA shall be done by Head QA for Approval or Rejection with sign and date.

6.7.2 After approval of Proposed CAPA, the proposed CAPA action plan shall be implemented by the Initiating Department.

6.7.3 In case of Approval / Rejection, CAPA Form shall be submitted to QA and same shall be Logged by QA with sign and date in **"Corrective Action and Preventive Action Record"** as Shown in **Annexure-II**.

6.8 POST IMPLEMENTATION EVALUATION & CLOSURE OF CAPA:

6.8.1 Post Implementation results of CAPA shall be compiled by Concerned Departments and shall be reviewed by Manager QA for its Implementation and completion along with review of documents and give comments for the Evaluation of CAPA along with sign and date.

6.8.2 CAPA shall be closed within 30 calendar days from date of Approval.

6.8.3 After post implementation evaluation of CAPA, Manager QA & Concerned Department Head shall sign and date for closure of CAPA.

6.8.4 Head QA shall further review the post implementation evaluation of CAPA for its correctness and completeness and shall close the CAPA with sign & date. Date of closure shall be mentioned by Head QA in CAPA form.

6.8.5 If proposed Corrective & Preventive Action(s) not achieved till target date then date shall be revised/extended after approval from Head QA and shall be documented in **"Extension Justification for CAPA Closure"** as shown in **Annexure-III** & respective Customer/Regulatory Agency shall also be informed.

6.8.6 The Extension Justification shall be Approved/Rejected by Head QA based on justification and revised Target Completion Date.

6.8.7 Any change proposed as a result of CAPA shall be through the current version of SOP **"Change Control Management"** SOP. Reference of the same shall be mentioned in the CAPA.

6.9 CAPA EFFECTIVENESS REVIEW:

6.9.1 After Closure of CAPA, it shall be reviewed to check the CAPA effectiveness.

6.9.2 CAPA effectiveness review date shall be 3 months from the closure date of CAPA, it shall be given by Head QA.

6.9.3 Effectiveness Review shall be done for the followings:

6.9.3.1 Repetition of the same non-conformance.

6.9.3.2 Occurrence of any other non-conformance which has the same root cause.

6.9.3.3 Any other impact of CAPA on systems which was previously not assessed.

6.9.4 Flow chart for Corrective & Preventive Action is shown in **Annexure-IV**, Titled **"Flow Chart for Corrective Action & Preventive Action"**.

6.9.5 Head QA shall give comments for CAPA effectiveness check along with sign & date for final closure of CAPA.

6.9.6 After Effectiveness review from Head QA, CAPA shall be closed by QA and same shall be documented in the CAPA Logbook and a photocopy reference copy shall be enclosed with respective Deviation, Batch Manufacturing Record, Batch Production Record, Internal Audit report, Change Control, Market Complaint, Product Recall and Incident Report etc.

6.10 CAPA TRACKING:

6.10.1 Tracking Corrective Actions and Preventive Actions shall be performed by respective QA Personnel.

6.10.2 For tracking, respective CAPA form and log shall be reviewed on regular basis by respective QA Personnel.

7.0 ABBREVIATIONS:

CAPA	Corrective Action & Preventive Action
cGMP	Current Good Manufacturing Practices
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Corrective Action & Preventive Action Form	
Annexure-II	Corrective Action & Preventive Action Record	

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Annexure-III	Extension Justification for CAPA Closure	
Annexure-IV	Flow Chart for Corrective Action & Preventive Action	

9.0 DISTRIBUTION:

- Master Copy — Quality Assurance Department
- Controlled Copy No. 01 — Quality Assurance Department.
- Controlled Copy No. 02 — Quality Control Department.
- Controlled Copy No. 03 — Production Department.
- Controlled Copy No. 04 — Warehouse Department.
- Controlled Copy No. 05 — Engineering Department.
- Controlled Copy No. 06 — Personnel & Administration and Human Resources Department.
- Controlled Copy No. 07 — Information and Technology Department.

10.0 REFERENCES:

- Draft Guidance to "WHO Deviation Handling and Quality Risk Management"; A note for guidance for the manufacture of prequalified vaccines for supply to United Nations agencies, July-2013.
- Guidance for Industry, "Quality Systems Approach to Pharmaceutical cGMP Regulations", September 2006.
- 21 Food and Drugs Chapter I, Food and Drug Administration Department of Health and Human Services Subchapter H -Medical Devices; Part 820 - Quality System Regulation, Subpart J, Corrective and Preventive Action.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I

CORRECTIVE ACTION AND PREVENTIVE ACTION FORM

CAPA No.	**:**	**Department**	**:**
Date	**:**	**CAPA Initiated by**	**:**

CAPA recommended as per →

Deviation No.	**:**	**OOS No.**	**:**
Incident No.	**:**	**Self Inspection**	**:**
Market complaint No.	**:**	**Trends analysis**	**:**
Product recall	**:**	**Annual Product Review**	**:**
Any other (Specify)	**:**		

Description of Non-Conformity

RCA : Applicable ☐ **Not Applicable** ☐

If Applicable, RCA No.:

Initiator
Sign/Date:

Investigation Findings:

Initiator:
(Sign/Date)

Review by: Head of Initiating Department
(Sign/Date)

CAPA Action Plan

Sr. No.	Corrective Actions	Responsible Department	Sign & Date	Target Completion Date

Sr. No.	Preventive Actions	Responsible Department	Sign & Date	Target Completion Date

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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* Attach separate sheet if required

Impact Assessment of the Proposed CAPA:

Review Comments:

Manager QA
Sign/Date:

Approval or Rejection of CAPA action plan	**Head QA** **Sign/Date**
Tick mark (✓ / X): **Approved** ☐ **Rejected** ☐	

Post Implementation Evaluation of CAPA (By Manager QA):
Review Comments:

Sign/Date:

Closure of CAPA action plan	**Sign/Date**
Initiator Department Head	
Manager QA	
Head QA	
CAPA Close out Date:	
Effectiveness Review: **CAPA Effectiveness Review Target Date:**	

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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Review Comments after CAPA Effectiveness check (By Head QA):

Sign/Date:

CAPA Report Closure by QA after Effectiveness Review:

CAPA Closed On:

Name: **Sign:** **Date:**

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ANNEXURE-II

CORRECTIVE ACTION AND PREVENTIVE ACTION RECORD

S .No.	Date	CAPA No.	Concerned Department	CAPA Issued By (Sign & Date)	Reference Doc. No.	Description of Non Conformity	CAPA Approved/ Rejected	Target Completion Date of CAPA	Close Out By QA (Sign & Date)	CAPA Effectiveness review by QA (Sign &Date)

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ANNEXURE-III

EXTENSION JUSTIFICATION FOR CAPA CLOSURE

Date:	
Department:	
Reference CAPA No.:	
Previous Due Date for CAPA:	
New Target Completion Date:	

JUSTIFICATION DETAILS
Open identified action of CAPA:
Justification:
Impact of delay: **Initiated By:** **Reviewed By: Head Initiating Department** **(Sign & Date)** **(Sign & Date)**
Approval / Rejection by Head QA: (Mark Tick √/x on applicable) ☐ **Approved** ☐ **Rejected** **Review Comments:** **Name:** **Sign:** **Date:**

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ANNEXURE-IV

FLOW CHART FOR CORRECTIVE ACTION & PREVENTIVE ACTION