DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Deviation	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for handling of deviations from approved procedure and standards.

2.0 SCOPE:

This SOP shall be applicable for deviations observed from laid down procedures and standards in Warehouse, Production, Engineering, Quality Control, Quality Assurance, Human Resources, Packaging Development, Documentation, etc. at ……..

3.0 RESPONSIBILITY:

The employee, who observes the deviation, shall report to his/her supervisor.

3.1 INITIATOR

3.1.1 To initiate the documentation of deviation in the format and to fill required information.

3.1.2 To initiate action for containment if required, and to notify department head and QA.

3.1.3 To ensure that affected material / product is appropriately contained, segregated and labeled.

3.1.4 To attach all available supporting documentation.

3.2 CONCERNED DEPARTMENT HEAD

3.2.1 To evaluate the deviation form received in consultation with QA.

3.2.2 To investigate the deviation and perform root cause analysis or potential cause of the deviation and suggest corrective and preventive actions.

3.2.3 To act in timely manner to limit the exposure of product involved with deviation (If required / possible)

3.2.4 To assist QA in the impact assessment of deviation on safety, identity, strength, quality, purity or potency of the drug product and / or its impact on facility, process, utility or equipment etc.

3.2.5 To train staff for recognizing, reporting and preventing deviations.

3.2.6 To ensure that the recommended CAPA(s) are initiated, monitored and completed.

3.2.7 To categorize deviation in consultation with QA.

3.2.8 Coordination with contract giver / external partner (If applicable).

3.3 QUALITY ASSURANCE:

3.3.1 Deviation login and numbering

3.3.2 To assist in investigation

3.3.3 To evaluate deviation reported

3.3.4 To evaluate adequacy of the investigation

3.3.5 To evaluate the impact of the deviation on safety, identity, strength, quality, purity or potency of the product of same batch, same product or other batches and products manufactured and/ or process, facility, utility and equipment.

3.3.6 To recommend to quarantine the product or materials affected (if required) until conclusion of required investigation (s).

3.3.7 Reviews the investigation report to ensure that :

3.3.7.1 Investigation conducted is satisfactory and identifies a root cause or potential reason for the deviation.

3.3.7.2 Adequacy of CAPA/s recommended, and its alignment with the probable root cause.

3.3.8 Reviews investigations, CAPAs and its Status Reports, effectiveness checks

3.3.9 Coordination with contract giver / external partner (If applicable).

3.4 HEAD QUALITY ASSURANCE

3.4.1 To evaluate suggested corrections and categorization of deviation are satisfactory.

3.4.2 To evaluate the investigation performed by initiator department and root cause(s)/ most probable cause(s) identified are satisfactory.

3.4.3 To evaluate the CAPA taken are satisfactory.

3.4.4 To evaluate the impact assessment performed are appropriate.

3.4.5 To approve the disposition decision.

3.4.6 To grant extension of investigation and CAPA implementation time lines.

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITIONS:

5.1 Deviation: It is a departure from Approved Procedure, Specifications or Protocols.

5.2 Investigation: A document analysis conducted to determine probable root cause, its immediate correction, corrective and preventive actions.

5.3 Impact Assessment

5.3.1 An assessment of the significance of the deviation on other batches /products / materials/ sites etc. containment actions (if required), acceptability of release (i.e. safety and efficacy), and justification for continuous manufacturing.

5.3.2 The action of assuring that all material that is potentially affected by a deviation is withheld from release / further distribution pending completion of an investigation or approved impact assessment. This also includes actions taken to immediately stop further occurrence of the unexpected event.

5.4 Correction: Action taken to correct single existing non-conformity, defect or other undesirable situation.

5.5 Probable cause: The identifiable factor (s) which is most likely to be responsible for the deviation, trend or result.

5.6 Root Cause: The most basic cause of a deviation and / or failure in a process, component or product.

5.7 Corrective Action: Action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.

5.8 Preventive Action: Action taken to eliminate the cause of a potential non-conformity, defect, or other undesirable situation in order to prevent occurrence.

5.9 Critical Deviations: Those deviations which are likely to have significant impact on quality of product or regulatory commitment or indicate critical failure of systems.

5.10 Major Deviations: Those deviations that could have a significant impact on quality of product or

regulatory commitment or indicate failure of a system.

5.11 Minor Deviations: Those deviations which are unlikely to have any detectable impact on quality of product or regulatory commitment or less serious observation /isolated incidence which do not indicate system failure.

5.12 Planned Deviation: It is the planned departure from established and approved procedures observed or noticed prior to the execution of an activity. No Critical or Major Planned Deviation shall be allowed, which has potential to alter the quality of the product, only Minor Deviations shall allow to plan.

5.13 Unplanned Deviation: It is the departure from any approved procedure, specification, protocols, process & system due to unforeseen situations while carrying out day to day activities. These deviations may occur for many reasons like Documentation errors, Equipment failure/breakdown/Malfunctioning, low yield, departure from SOPs & written Procedures.

6.0 PROCEDURE:

6.1 INITIATING A DEVIATION FORM :

6.1.1 Initiator/Supervisor shall raise request for issuance of "Deviation Form".

6.1.2 Initiator shall fill the Deviation Form and write the following Details:

6.1.2.1 Description of Deviation

6.1.2.2 Date of Occurrence of Deviation

6.1.2.3 Type of Deviation (Planned or Unplanned)

6.1.2.4 Mention whether Deviation is related to Procedure, Process, Equipment, Standard, Batch size, Low yield or others

6.1.2.5 If Deviation is related to Product, mention the name of product, batch number, Mfg. date, Exp. Date, Batch size & Market.

6.1.2.6 Justification/Rationale of deviation

6.1.3 Initiator of the deviation shall put his / her name, signature with date in the Deviation Form.

6.1.4 Forward the duly filled deviation Form to Department Head for his review and evaluation. Department head shall put his comments. Department Head shall put his / her name and signature with date.

6.2 DEVIATION NUMBERING

The Quality Assurance Department assigns tracking number to deviation as follows:

Deviation Number: …….

Where

DV stands for Deviation.

XY stands for last two digit of respective year (i.e.) 15 indicates the Year 2015,16 indicates the year 2016 and 17 indicates the year 2017 and onwards.

\- stands for separator

001 stands for the continuous serial number of respective deviation in the respective year.

6.3 CONDUCTING DEVIATION INVESTIGATION

6.3.1 Concerned Department Head in consultation with Department QA shall conduct an investigation & root cause analysis (RCA) according to SOP.

6.3.2 RCA Number shall be mentioned in Deviation Form. For Planned Deviations no RCA is required, only justification and target completion date for the planned activity shall be mentioned.

6.3.3 Deviations investigations shall be performed and product disposition decisions shall be taken as early as possible not exceeding 30 calendar day from the date of deviation log in.

6.3.4 Target date for completion of investigation shall be mentioned in the Deviation Form.

6.3.5 Investigation report shall be prepared. Investigation findings and root cause identified shall be recorded / attached in the Deviation Form.

6.3.6 Deviation Form shall be forwarded to other concerned department for evaluation of investigation, if required.

6.3.7 NOTIFICATION TO CUSTOMER/REGULATORY AGENCY:

6.3.7.1 Concerned Customer/Regulatory Agency shall be notified if any Deviation is applicable, which may have impact on the product quality to seek their acceptance. It is necessary to first get approval from the Concerned Customer or Regulatory Agency through scan copy / hard copy of Deviation Form. Signed scan copy shall be attached with Deviation Form than only Deviation shall be proceeding for Approval by Head QA.

6.4 OBTAINING DEVIATION EXTENSION FOR INVESTIGATION

6.4.1 If circumstances do not allow investigation closure within 30 calendar days from date of deviation login, the investigation team shall request for an extension to the QA Head with reason for extension, progress as on date and New Target date as per Interim Report (Annexure III) but in case of Planned Deviation a target date of completion shall be given at the time of originating the deviation.

6.4.2 Head QA shall review the request for extension and may grant additional time to close out the report by approving and signing the interim report.

6.5 CATEGORIZATION OF DEVIATION

6.5.1 Based on Investigation findings Department Head and QA shall assess the risk of deviation with respect to detectable impact on quality of the product, regulatory commitment or system failure.

6.5.2 Department Head and QA shall categorize the deviation as

- Critical
- Major
- Minor

6.6 IMPACT ASSESSMENT

6.6.1 Concerned Department Head & QA shall evaluate impact of deviation on quality of product and record the same in Deviation Form.

6.6.2 During impact assessment it shall be evaluated if other products/batches/equipment/validation/ qualification/activities have any impact and shall make suitable recommendations under impact assessment in the format.

6.6.3 In case of Critical Deviations risk assessment shall be performed as per SOP and shall be attached with deviation form.

6.6.4 For Critical Deviations which have direct impact on product quality, QA Head shall be responsible to give decision regarding batch hold or rejection.

6.7 CORRECTIVE ACTIONS & PREVENTIVE ACTIONS (CAPA)

6.7.1 Based on investigation, Concerned Department Head shall suggest corrective and preventive actions to remedy the root / most probable cause(s) and record the same in the Deviation Form.

6.7.2 For CAPA follow the Procedure mentioned in SOP.

6.8 FINAL EVALUATION OF DEVIATION

6.8.1 QA Head shall review the investigation report for adequacy of root / most probable cause(s) identified, categorization of deviation based on risk involved, impact assessment and corrective / preventive actions recommended.

6.8.2 QA Head shall evaluate and put comment if the product is acceptable or not acceptable for release, by ensuring all corrections are completed and corrective and preventive actions are tracked through CAPA.

6.8.3 QA Head shall approve/reject the deviation with comments.

6.9 HANDLING OF DEVIATION FORM

6.9.1 After disposition decision by QA Head, get the photocopy of the deviation form and forward original copy to QA department for further retention.

6.9.2 Initiating department shall file the photocopy of the approved deviation form with the respective product batch record/affected document.

6.9.3 Send a copy of deviation to regulatory affair department, wherever comments of the regulatory affairs department are taken; as information and for further action (s) if any.

6.9.4 For initiation of Planned Deviation follow the Procedure given in steps 6.1 & 6.2

6.9.5 In case of Planned Deviation Concerned Department shall give the Justification/Rationale and enclose supporting data if required. Details of no. of batches shall be mentioned in Deviation Form.

6.9.6 Investigation & RCA is not required for Planned Deviations.

6.9.7 If same planned deviation is repeated for 3 times or likely to be permanent then it shall be done through change control, which shall be recorded in Deviation Form. Target completion date for planned deviation shall be mentioned in Deviation Form by Concerned Department.

6.9.8 Planned Deviation shall be implemented after approval from QA.

6.10 VERIFICATION OF CAPA

6.10.1 Department Head/Designee of initiating department shall initiate and follow up for the suggested corrective & preventive action (s).

6.10.2 Department Head and QA shall monitor the implementation of suggested corrective and preventive action (s).

6.10.3 If suggested CAPA is not completed within 30 Calendar days from the date of Approval then Interim Report (as per Annexure-III) shall be generated detailing the reason for extension, progress as on date, new target date as per Interim Report.

6.10.4 QA Head shall review the interim report and may grant additional time to close out the CAPA by approving and signing the interim report.

6.11 CLOSING OUT DEVIATION

6.11.1 Deviation Form shall be closed within 30 Calendar days from date of Approval.

6.11.2 Head QA/Designee on verification of implemented CAPA which is suggested in Deviation Form shall close the deviation by his/her signature with date.

6.12 TRENDING OF DEVIATION

6.12.1 Documentation QA shall carry out trend analysis of the deviations quarterly according to **SOP** for the number of major, minor & critical deviations logged in.

6.13 Deviations shall be reviewed and evaluated by Head QA as part of the periodic product review processes as described in the procedure of **"Annual Product Review",** Assessment shall be made of any trends or underlying issues that may require additional corrective/preventive action to be taken or any improvement to the system/process to prevent reoccurrence.

6.14 Any amendments to systems, documents or operating procedures arising out of the recommendations for corrective and preventive actions shall be done according to the procedure of **"Change Control".**

7.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
PD	:	Planned Deviation
UD	:	Unplanned Deviation
C.C. No.	:	Change Control Number
NA	:	Not Applicable
CAPA	:	Corrective Action & Preventive Action
SME	:	Subject Matter Expert
RA	:	Regulatory Affairs

8.0 ANNEXURES:

Annexure I	Deviation Form	
Annexure II	Deviation Log book	
Annexure III	Interim report	
Annexure IV	Flow chart deviation reporting	

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 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department.

10.0 REFERENCES:

IN HOUSE

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

DEVIATION FORM

Deviation No.:		**Date of Issuance:**	
Initiator Name:		**Department:**	
Deviation Type (Encircle one)	Planned / Unplanned	**Date of Occurrence**	
Product Name		**Batch Number**	
Mfg. Date:		**Expiry Date:**	
Batch Size:		**Market:**	
Deviation related To(mark ✓):	**Procedure** ☐ **Process** ☐ **Equipment** ☐ **Standard** ☐ **Batch Size** ☐ **Low Yield** ☐ **Others** ☐		
Details of Deviation: **Initiator Signature:** **Date:**			
Justification /Rationale: **Initiator Signature:** **Date:**			
Complete the following details in case of Planned Deviation: Deviation is likely to permanent: Yes/No (If Yes Change Control No.:) No. of batches/studies:…… Target date of completion: …….			

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Review by Concerned Department Head:
Comments:

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

Investigation & Root Cause Analysis (RCA) as per SOP No.: .....
If Applicable RCA No.: **Target Completion Date:**

Concerned Department Head
Sign & Date:

Other Concerned Departments Comments (if necessary):

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

Approval from Concerned Customer/Regulatory Agency (If Applicable):

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

Category of Deviation (mark ✓):

Major ☐ **Minor** ☐ **Critical** ☐

Impact Assessment & Risk Assessment (If required):

Concerned Department Head
Sign & Date:

Quality Assurance
Sign & Date:

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Corrective Action(s) and Preventive Action(s):

Concerned Department Head
Sign & Date:

Approval/Rejection of Deviation:
Comment:

Conclusion: Deviation is Approved / Rejected

Head QA:
(Sign & Date)

Close Out by (Quality Assurance)

Verification of Corrective Action/Preventive Action Taken:
Remarks:

Head QA:
(Sign & Date)

Date of Closure:

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ANNEXURE-II

DEVIATION LOG BOOK

Sr. No.	Deviation No.	Date of Initiation	Originating Department	Deviation Type PD/UD	Affected Product/Material	Affected Batch Number /A.R.Number	Description of Deviation	Deviation Closed on	Sign of QA/ Date	Remark

ANNEXURE-III

INTERIM REPORT

FROM :_____

To : **QUALITY ASSURANCE**

Reference Deviation No.:

Description of Deviation:

Suggested Corrective Action and Preventive Action:

Committed Target Date:

Reason for Extension:

Progress as on date:

New Target Date

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ANNEXURE-IV

FLOW CHART