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<b>TITLE: HANDLING OF DEVIATIONS</b>				

## 1.0 PURPOSE:

To lay down the procedure to describe reporting, handling, investigation, closure and documentation of deviations occurring in the manufacturing process or to approved procedures and systems.

## 2.0 SCOPE:

The procedure applicable for all deviations from approved procedures related to testing, manufacturing, packaging, storage, issuance of material related to Raw materials, Intermediates and documentation systems at Discovery Laboratories Pvt. Ltd.

## 3.0 RESPONSIBILITY:

3.1 Initiator: The person who has noticed the deviation(s) shall report to his/her immediate superior and in consultation with shift in-charge / immediate supervisor shall document the deviation with appropriate reasons and action taken in the Deviation Report form, QA012-FM002 to QA department. This should be done within 24hours.

3.2 It shall be responsibility of QA personnel:

3.2.1 To allot deviation report number, log in deviation in the register, retain completed documents pertaining to the deviation, which includes the minutes of any meetings, investigation reports, follow-up reports of Corrective action and Preventive action (CAPA).

3.2.2 QA personnel shall involve in the investigation along with initiating department.

3.3 It shall be responsibility of the Head-Initiating Dept / designee.


3.3.1 To investigate the causes of deviation and assess its impact on product quality.

3.3.2 To make appropriate conclusions and proposals for CAPA in consultation with the Head-QA and other concerned departments.

3.3.3 To the implementation of CAPA as mentioned in the deviation report.

3.4 It shall be responsibility of the Head-QA / designee, as appropriate:

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- 3.4.1 Review and approve the deviation report (classification details, immediate action, investigation, root cause, Corrective and Preventive action etc).
- 3.4.2 Determine the product impact and make the decision on the product disposition in consultation with Head-initiating department.
- 3.4.3 Review and verify the accuracy and completeness of investigations performed.
- 3.4.4 Assess and close the deviation report.
- 3.4.5 To provide disposition of materials and products affected by deviation and ensuring that the conclusions are supported by adequate documentation.
- 3.4.6 To monitor the implementation of CAPA.

#### 4.0 DEFINITIONS:

- 4.1 **Deviation:** Any occurrence, problem (or) undesirable event (product or non-product related), that represents a departure from what is required, expected or acceptable in a GMP system. Events that pose potential risk to the; identity, strength, quality, purity, safety, efficacy, performance, reliability or durability of the drug. for e.g.:
  - 4.1.1 A non-compliance with an approved procedure related to GMP governed processes and systems for example manufacturing, manufacturing support, distribution or quality functions.
  - 4.1.2 Results that fail to meet in- process control limits.
  - 4.1.3 Malfunction of equipment, instruments, or systems during production related activities.
  - 4.1.4 GMP equipment or instrument out of tolerance events or calibration failures.
  - 4.1.5 Environmental monitoring and microbial action level excursions.
  - 4.1.6 Computer system events, in which GMP relevant data is lost, corrupted, or the system does not perform as required.
  - 4.1.7 Other event(s) that may pose potential risk to the drug substance.
  - 4.1.8 Deviations are not:

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a) Events that occur as an inherent part of the procedure or process and where the procedure defines how to deal with the event in a controlled manner.

b) Data recording errors that can be verified with documentation or corrected in accordance with local procedures.

4.2 **Corrective Action:** Action taken to eliminate the causes of Non-conformities, in order to prevent re occurrence.

4.3 **Preventive Action:** Action to eliminate the cause of potential Non-conformities in order to prevent occurrence.

4.4 **Planned deviation:** A deviation that is planned when unexpected condition makes it impossible to comply with the existing quality expectations.

## 5.0 PROCEDURE :

### 5.1 Deviation Reporting (Initiating Department):

5.1.1 Whenever any deviation with respect to process (or) system has been observed, it shall be reported to the immediate superior.

(Typical examples of deviations with respect to practice are given in Annexure – I).

5.1.2 User departmental personnel in consultation with Shift in-charge / supervisor shall request Deviation Report Form (QA012-FM002) to QA.


5.1.3 The initiating departments then fill the Deviation Report QA012-FM002 with the following details.

5.1.3.1 Name of the Department and Date of deviation.

5.1.3.2 Indicate the Area of deviation as Process, Equipment, System or others. Give additional information and specify details of Product / Equipment / Document name with Stage and Batch Numbers / Equipment ID number and Document number as applicable.

5.1.3.3 Description of the deviation against the standard practice with reason.

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5.1.3.4 Immediate action shall be recorded in ‘Details of Immediate Action Column’.

## 5.2 Deviation Assessment (Quality Assurance):

5.2.1 The Deviation Report with the above mentioned details shall be forwarded to the QA personnel within 24 hours of reporting of deviation.

5.2.2 Concern personnel in QA shall allot the deviation number as per log. Enter the details deviation log as form QA012-FM085 (i.e. Deviation date, Department & Deviation Report Number).

5.2.3 QA shall allot an unique identification number DR-XX-YYZZZ,

Where, DR - stands for Deviation Report

XX - stands for the Department Code

ZZZ - stands for the Sequential No. 001,002,

YY - stands for the last two digits of the Year

Ex.: DR-PD-19001 represents the first deviation reported in site and it is related to Production department.

5.2.4 The deviation report shall be forwarded to Head-QA / Designee.

5.2.5 Head-QA/Designee shall review the nature of deviation, reason and action taken.


5.2.6 Head-QA/ Designee shall assess the impact of the deviation on the product quality.

5.2.7 Depending upon the impact assessment, further processing (or) continuation of the activity shall be finalized.

5.2.8 QA representative shall review the nature of deviation, and shall be classified on the basis of impact as Critical, Major and Minor deviation;

5.2.8.1 **Critical:** A deviation that has substantial potential to have an adverse impact on the Identity, strength, quality or potency of a product or produce a product which is not in accordance with the specifications or technical agreement/regulatory requirement.

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5.2.8.2 **Major:** A deviation that may have impact on the identity, strength, quality or potency of product is not in accordance to standard specified but not from technical agreement/ regulatory requirement.

5.2.8.3 **Minor:** A deviation that may not have any adverse impact on the identity, strength, quality or potency of a product, it is due to a departure from approved procedures.

5.2.9 QA shall check whether the problem is repetitive for a particular product or system, if so, necessary actions should be taken to eliminate the frequent failure of the reported process / system.

### 5.3 Investigation:

5.3.1 The concerned department performing an investigation must ensure the thoroughness and accuracy of the investigation. Investigation should include the review of any similar deviations occurred during the previous year.


5.3.2 If identified the re-occurrence the same shall be addressed in the investigation report.

5.3.3 The investigation team shall verify, the triggered deviation shall impact the quality on subsequent batches.

5.3.4 Head-QA (or) Designee shall initiate an investigation to substantiate the causes of deviation and identify potential factors leading to the deviation (root cause). The investigation shall include the verification of material and documents of inter related departments, practice against standard procedures, training and performance of the personnel etc., to evaluate a reason for the deviation.

5.3.5 The product history shall be considered as part of investigation to verify similar deviations in past and also assessment shall be done for the impact on subsequent batches.

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5.3.6 Deviations which impact the quality of the product, various factors like regulatory submissions, effect on subsequent batches, impact on customer agreement etc., needs to be evaluated. Depending upon the outcome of the investigation, wherever necessary additional analysis, and or short term stability studies shall be conducted.

5.3.7 Based on the root cause, the Corrective action and Preventive action shall be proposed by Head-Initiating dept / Designee consultation with Head-QA / Designee and the other concerned departments.

5.3.8 All the deviations shall be closed within 30 days reporting of the deviation. Agreed CAPA in the investigation shall be tracked for implementation. If a deviation investigation will not close within 30 days, requisition for extension of deviation for more than 30 days form (QA012-FM141) shall be prepared by Initiating department followed by Head-QA or Designee approval and attach to the Deviation Report.

5.3.9 Deviation report should give the reference of identified probable route cause, Corrective and Preventive actions and the closure statement should be documented.

#### 5.4 Closure of Deviation Investigation:


5.4.1 QA shall review the completed investigation including identified route cause and proposed CAPA(s).

5.4.2 Based on the investigation, identified root cause, impact assessment and if appropriate, agreed corrective actions, QA determine or decide on the product disposition.

5.4.3 If QA agree with the completed investigation, root cause and proposed CAPA(s), giving details of product disposition, the investigation reports can be signed off and the deviation shall be closed. QA representative shall update the deviation log.

5.4.4 Head-QA / Designee shall also ensure the implementation of the CAPA and their recording as per the procedure on Corrective and Preventive action at site.

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5.4.5 Head-QA or designee shall review the deviations on periodic basis for once in a month against parameter related to product quality and manufacturing process to verify the effectiveness of the CAPA taken.

5.4.6 In case of deviation related to manufacturing process, it shall be recorded in the respective page of the Master Batch Production Control Record along with the reference to the Deviation report number.

### 5.5 Planned Deviation:

5.5.1 Planned deviation concept is being applied to post validated processes/post approval processes etc. for the reasons such as process improvement, exigencies in manufacturing, equipment and batch size, etc.

5.5.2 The description of all the changes being taken up for study shall be discussed in detail with the respective customer/applicant and the planned deviation study shall be undertaken only with the prior consent for respective clients.

5.5.3 Concerned department head / supervisor shall write a planned deviation report in a prescribed form for any planned deviation in Process, facility, equipment, material, etc.

5.5.4 Details of the proposed deviation and reason for deviation shall be given in the planned deviation report.

5.5.5 The Quality Assurance personnel shall enter the details of planned deviation in the planned deviation log and assign a planned deviation report number. For operational convenience, log books shall be maintained department specific.

5.5.6 Planned Deviation Report number shall be assigned as PDR/XXX/YYNNN, where,


PDR: Planned deviation report

XXX: Product code along with stage or department code

YY: Last two digits of the year

NNN: Serial number

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Eg. PDR/PD/19001

5.5.7 QA representative shall be review planned deviation and approved the planned deviation if satisfactory.

5.5.8 Initiating department made a conclusion, after implementation of planned deviation and submitted to QA for closure.

5.5.9 QA shall review the post planned deviation report make a closure comments and notify to customer if required.

## 6.0 FORMATS / ANNEXURE(S):

6.1 Deviation Report : QA012-FM002

6.2 Deviation Log : QA012-FM085

6.3 Planned deviation Form : QA012-FM147

6.4 Planned deviation log : QA012-FM148

6.5 Requisition for Extension of deviation for more than 30 days : QA012-FM149

6.6 Annexure-1 : Typical Examples of Deviations

6.7 Annexure-2 : Flow Chart for Handling and Investigation of Deviations


## 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	Formats are the part of SOP. So prepared Separately and more clarity.	---
03	01-08-2016	Laboratory incidents are mention in this SOP.	---

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Revision No.	Effective Date	Details of Revision	Ref. CCF No.
04	20.02.2017	<ol style="list-style-type: none"> <li>1. SOP format changed make to inline with QA/SOP/001-04.</li> <li>2. Typical Examples of Deviations included as a Annexure-1.</li> <li>3. Flow Chart for Handling of Deviations from included as an Annexure-2.</li> <li>4. Contents in the Deviation report and Deviation log has been modified for better clarity.</li> <li>5. Responsibilities are elaborated. Classification of deviations included.</li> <li>6. Requisition for Extension of deviation for more than 30 days form included.</li> <li>7. CAPA handling procedure removed and prepared as separate SOP.</li> <li>8. Laboratory incidents procedure removed.</li> <li>9. Planned deviation procedure included.</li> <li>10. Altogether procedure has been rephrased for better clarity.</li> </ol>	QA-CRF-001/17
05	01.01.2018	<ol style="list-style-type: none"> <li>1. SOP format changed make to in line with SOP-QA-001-05.</li> <li>2. Classification of Deviations are Removed.</li> <li>3. Altogether procedure has been rephrased for better clarity.</li> </ol>	CCF/GEN/17037
06	30.05.2019	<ol style="list-style-type: none"> <li>1. Deviations classified as Critical, Major and Minor.</li> <li>2. Investigation procedure elaborated for the better clarity.</li> </ol>	CCF/GEN/19007
07		<ol style="list-style-type: none"> <li>1. Section 5.4.5 has been elaborated to include the deviations periodic review frequency for once in a month.</li> <li>2. Periodical review report for Deviations template has been introduced.</li> </ol>	

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