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 a procedure for Handling of Deviation.

2.0 SCOPE:

This SOP is applicable to handling of deviations to approved/established procedures such as Batch Manufacturing Records/Batch Packing Records, SOP's, STP's, calibration procedures and specifications or other established procedures or systems.

3.0 RESPONSIBILITY:

Head – Concerned department

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Preparation procedure :

5.1.1 Deviations can be two types and are defined as below.

5.1.2 (A)Unplanned deviation: It may arise due to break down or failure of (a) an equipment (b) malfunctioning of an Instrument (c) Utility/Service (d) Human error or (e) any other.

5.1.3 (B)Planned deviations: Planned deviation shall take place only for quality improvement, yield improvement, better GMP's, safety reasons and market requirement. For example, Improvement in yield/quality, safety, batch cycle time reduction, cost, improve GMP and compliance to regulatory commitments

5.2 **Unplanned Deviation:**

5.2.1 Unplanned deviation shall be brought to notice by operator/supervisor to the head of department.

5.2.1 Head of the Department shall inform QA, to get deviation form issued.

5.2.2 Head of the Department upon primary investigation shall write his comments on unplanned deviation along with the proposed corrective action(s).

5.2.3 Head of the Department shall forward the unplanned deviation to Plant Manager for review.

5.2.4 Plant manager shall review the nature of deviation, the reason for deviation, and the primary investigation and comments given by the HOD. He shall suggest the corrective actions and forward the same to QA.

5.2.5 Head – Quality Assurance or his designee shall review the impact of deviation on the product quality, process performance, yield, GMP or required regulatory commitments, analytical requirements and any similar deviations in past.

5.2.6 QA -Head shall assess the un planned deviations and the corrective actions suggested by the plant Head, and shall recommend the additional testing(s), preventive and corrective steps on product / process if required, based on the validation data and past experience. Based upon the assessment of the corrective actions planned/taken, QA Head shall decide for any change in the facility/ system through the change control procedure.

5.2.7 The final decision shall be written by QA -Head on unplanned deviation report with signature and date.

5.2.8 Quality Assurance shall assign a number to the unplanned deviation report as per Annexure –I and record the details in deviation register as per Annexure-III.

5.2.9 Unplanned deviation report can be numbered as follow;

UDR/2101

Where,

UDR : Denotes “Unplanned Deviation Report”

/ : Slash

21:Year of 2021

01: Serial no. of deviation

5.2.10 Released The unplanned deviation shall be closed by head of department in consultation with QA -Head before batch is approved.

5.2.11 Quality Assurance department shall file the original closed deviation record and a copy of the same shall be filed in the affected Batch records.

5.3 Planned Deviation:

5.3.1 Planned deviations are identified by head of department, when there is going to be a change in

location / area, change in equipment(s) to be used, change in quality of raw material, packaging material, change in processing step, in change in control limit, change in packaging material, change in STP, change in testing condition, change in sampling procedure, change in steps of SOP, or any other established parameter(s) / determined by Quality Assurance.

5.3.2 Head of Department shall discuss with Quality Assurance before initiating planned deviation.

5.3.3 In case of process changes, planned deviation shall be approved only, when supported by the laboratory data.

5.3.4 The planned deviation shall be with prior approval from Quality Assurance

5.3.5 The planned deviation shall be initiated by responsible person of the concerned Department as per Annexure–II. This shall include the information related to the planned deviation, standard practice and reason for deviation. The planned deviation shall then be evaluated and commented by HOD.

5.3.6 Head of Department shall send back planned deviation to responsible person if not satisfied with reasons for deviation. If found satisfied, with necessity, he shall recommend time frame of deviation and send to Plant Manager for evaluation.

5.3.7 After evaluation, Plant head forwards the same to QA for review and evaluation.

5.3.8 Quality Assurance shall review the deviation for acceptability and impact on product quality, process performance, yield, analytical, GMP's, or regulatory and decide to allow or not to allow the proposed deviation. During evaluation it is ensured that, unclosed unplanned deviation (eg. related to machine breakdown) shall not be approved.

5.3.9 Quality Assurance may consult formulation development depending upon the nature of deviation (if any).

5.3.10 Quality Assurance may consult regulatory affairs, if any deviation to regulatory commitments / major changes. In case of products for the regulated market, the deviation shall be done only after seeking approval from the respective regulatory authority.

5.3.11 Based upon the repetition of the planned deviations and their assessment, QA Head shall decide for applicability of the change in the facility/ system through the change control procedure.

5.3.12 If Quality Assurance decides to approve, Head – Quality Assurance shall give recommendations, suggest alternatives and propose corrective action. This might lead to additional testing(s) / precaution(s).

5.3.13 Number shall be assigned to approve planned deviation report. The rejected planned deviation shall not have any number.

5.3.14 Deviation report can be numbered as follow;

PDR/2101

Where,

PDR: Denotes "Planned Deviation Report"

/ : Slash

21: Year of 2021

01:Serial no. of deviation

5.3.15 After approval, Head of the Department shall undertake the activity as per time frame.

5.4 Closure:

5.4.1 The outcome on planned deviation shall be reviewed, documented and closed by head of department in consultation with Quality Assurance.

5.4.2 Quality Assurance shall decide whether change is to be made permanent. If yes, it shall made through "Change Control Form" as per change control SOP.

5.4.3 If review calls for extension in time frame, this shall be further recommended by department and approved by Head – Quality Assurance.

5.4.4 Quality Assurance shall preserve original copy and the copy of the same shall be filed along with Batch records or related documentation in which deviation is taken.

5.4.5 Head-QA will take the batch release decision subject to additional testing required, if any, at the end of the batch completion.

5.4.6

6.0 ABBREVIATION(S):

GMP : Good Manufacturing Practice

R & D : Research and development

SOP : Standard operating procedure

7.0 REFERANCE(S):

NA

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

8.0 ANNEXURE(S):

ANNEXURE – I : Unplanned deviation Form

ANNEXURE – II : Planned deviation Form

ANNEXURE- III : Deviation Register

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

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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

Annexure I

UNPLANNED DEVIATION FORM

Initiated By:	**Department:**	**Date:**
Deviation No.:	**UDR/**	
Deviation Related To	☐ Equipment/Instrument ☐ Utility/Service ☐ Human Error ☐ Others	

Nature of deviation

Reason for Deviation

Primary Investigation and Comment (HOD)

Sign :	**Date:**

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

Corrective actions as suggested by Plant Head

Sign :	**Date:**

Review and Evaluation by Quality Assurance:

Product Quality Impact	Yes/No
Process Performance Impact	Yes/No
Yield Impact	Yes/No
GMP Impact	Yes/No
Additional Testing Required	Yes/No
If yes, then mentions	
Any similar deviation/past experience	Yes/No

Assessment and Corrective Action by QA Head

Sign:		**Date:**

Closure:

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

All check points compiled with (Documentary evidence shall be attached or referred to)	Yes/No
Deviation shall be corrected and closed before batch is approved/released	Yes/No
Based upon the assessment of the corrective actions planned, whether change control is required.	Yes/No
Batch release satisfactory	Yes/No
Other (Specify)	

Closure:	Affected documents closed: Yes/No
Head Of Department	
Sign:	Date:
Approved by – Head (Quality Assurance)	
Sign:	Date:

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

Annexure II

PLANNED DEVIATION FORM

Initiated By:		Department:	Date:
Deviation No.:		PDR/	
Deviation Related To	☐	Location/Area	
	☐	Equipment	
	☐	Raw Material	
	☐	Packaging Material	
	☐	Manufacturing	
	☐	Packaging	
	☐	STP/GTP/Specification/SOP	
	☐	Others	
Deviation Planned			
Standard Practice			
Reason for Deviation			

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

Review and Comments (HOD):

If approved : Time frame for deviation : ___ to ___		
Sign :		**Date** :

Evaluation by Plant Head:

Sign :		**Date** :

Review and Evaluation (Comments) by Quality Assurance:

Product Quality Impact	Yes/No
Process Performance Impact	Yes/No
Yield Impact	Yes/No
GMP Impact	Yes/No
Additional Testing Required	Yes/No
If yes, then mentions	
Any similar deviation/past experience	Yes/No
Incase of repeated deviation, whether Change control is applicable and is filled	Yes/No
Planned deviation is to be made permanent	
Regulatory evaluation required	Yes/No

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

Evaluation by Head – Regulatory Affairs:

Regulatory Impact	Yes/No
Notification to Regulatory agency required	Yes/No
Sign:	Date:

Recommendation **Alternatives** **Corrective Actions**	**:** **:** **:**	**Deviation**: **Approved/Rejected**.
Head–Quality Assurance	:	Signature: Date:

Closure	:	
Planned deviation is to be made permanent	:	**Yes/No**
Change control form is filled	:	**Yes/No**
Other (Specify)		
Planned deviation closed	:	**Yes/No**
Head of the Department	:	Signature: Date:
Head - Quality Assurance	:	Signature: Date:

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

Annexure III

DEVIATION REGISTER

S.No.	Date of Notification	Initiating Department	Deviation details	Stage	Reasons for deviation	Corrective Actions	Approval	Deviation No.	Remarks