DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a procedure for the Instruments which are found out of calibration.

2.0 SCOPE:

This SOP is applicable to all the instruments and measuring devices in……., which are under calibration program.

3.0 RESPONSIBILITY:

Officer/ Executive- Respective Department

Head- Respective Department

Head-Engineering.

Head-Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1.1 Perform calibration of instrument or measuring device as per the procedure given in respective SOP of the instrument.

5.1.2 During calibration if the results are found out of calibration, then immediately stop using the same and label it as 'UNDER MAINTENANCE'.

5.1.3 Immediately inform to Head of Department for the further action.

5.1.4 The Officer/Executive shall raise an Out of Calibration Evaluation form (Annexure-I).

5.1.5 The investing team including the Head of the Department or the designee shall review the following under the guidance of Head Quality Assurance.

Degree of out of calibration and criticality of the result

- Any supporting data like system suitability, system performance or back up data
- Impact analysis for the product, process that is analyzed/measured during the period of last calibration and the current calibration.

5.1.6 The Head-QA shall design the action plan based on the review and make report that includes:

- The calibration findings, instrument used for the calibration and its calibration status, instrument traceability.
- The degree of failure (the level of out of calibration from standard) this will use in the deciding the action plan.
- The impact of failure on products, which are analyzed, and or process, which are measured. This can be done by reviewing but not limited to sequential log, instrument usage log, equipment history card and mention in the column.
- Analysis of control sample or in-process sample (if the process is on going) for the specific tests using the instrument or devise.

5.1.7 In case other supporting data are available which can justify the impact, it may not be necessary to analyze the entire impacted product. This needs to clearly mention in the action plan and justified.

5.1.8 The Head-QA shall implement the action plan and after completion of implementation of plan, the team shall review the data and appropriate action shall be decided for the affected product. This may be but not limited to the product recall, information to customer if failure of sample analysis.

5.1.9 Out of calibration incidence shall be closed out by Head QA after thorough review of action plan, execution, data review, and action based on the findings. Conclusion shall be drawn.

5.1.10 The section Head shall initiate a parallel activity to rectify the instrument/measuring device and recalibration shall be performed before putting in actual practices.

5.1.11 Record the out of calibration evaluation as per Annexure-I.

6.0 ABBREVIATION(S):

QA: Quality Assurance

QC : Quality Control

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure-I: Out of calibration evaluation form.

9.0 REVISION CARD:

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

Annexure I

Out of Calibration evaluation form

Instrument/measuring device	**Identity No.:**
Department:	
Date of previous calibration:	**Previous calibration status:**
Date of current calibration:	**Calibration status:**
Calibration findings:	
Degree of failure:	
Impact analysis: (attach a separate sheet if necessary):	

On product	On process

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Action plan

(1) For Additional analysis (Attach separate sheet if required)

Product Name	Batch No.	Test applied	Results	Remarks

(2) Others if any:

Review of Action:

Closing of Out of calibration (Attach all supporting data, if any)

Checked By		**Approved and Closed By**
Department Head	**Head- Engineering**	**Head – QA**