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:**
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1.0 PURPOSE

To lay down a procedure for reporting and handling of the out of calibration situation arising after performing the scheduled calibration.

2.0 SCOPE

2.1 This standard operating procedure (SOP) is applicable for both laboratory instruments and instruments used in manufacturing/engineering/warehouse equipment.

2.2 This SOP is also be followed in case a process failure investigation leads to out of tolerance values of a particular instrument.

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 In-House

3.2 Attachments

3.2.1 Attachment -I : Out of Calibration Evaluation Form Issuance Register.

3.2.2 Attachment-II : Out of Calibration Evaluation Form

3.2.3 Attachment-III : Flow Chart of OOC

3.2.4 Attachment-IV : Master Calibration Schedule- In house

3.2.5 Attachment-V : Master Calibration Schedule- External

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Calibration**

The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring, recording & controlling, or the values represented by a material measure, & the corresponding known values of a reference standard.

4.1.2 **Assignable cause**

A cause that has been identified as the reason to invalidate a test result. The assignable cause is a conclusion derived from direct or indirect evidence found during the investigation process, from the interpretation of data or combination of both.

4.1.3 **Out of Calibration**

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The results which does not meets the pre-established acceptance criteria for the particular instrument or device calibration is termed as Out of calibration result.

4.2 Abbreviations

4.2.1 HOD: Head of the department

4.2.2 QC: Quality Control

4.2.3 QA: Quality Assurance

4.2.4 SOP: Standard operating procedure

4.2.5 OOC: Out of calibration

5.0 RESPONSIBILITY

5.1 Concern Department Person:

5.1.1 To calibrate the instrument as per calibration schedule.

5.1.2 To record all the data as per defined system.

5.1.3 To intimate the Head of department about the Out of Calibration.

5.1.4 To prepare in-house and external master calibration schedule.

5.2 Concern Department Head

5.2.1 To register the Out of calibration events and issue out of calibration evaluation form.

5.2.2 To arrange for instrument / equipment repair / replacement and review calibration data.

5.2.3 To investigate out of calibration as per defined system.

5.2.4 To instruct concern person for doing calibrations as per investigation flow.

5.2.5 To conclude the investigation and impact analysis of Out of calibration.

5.2.6 To recommend corrective and preventive action.

5.2.7 To check the in-house and external master calibration schedule.

5.3 Engineering Head

5.3.1 To arrange for instrument / equipment repair / replacement.

5.3.2 To help investigate out of calibration as per defined system.

5.3.3 To conclude the investigation of Out of calibration.

5.3.4 To recommend corrective and preventive action.

5.4 Head QA

5.4.1 To investigate out of calibration as per defined procedure.

5.4.2 To guide for further investigation and/or action, wherever require.

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5.4.3 To Approve the out of Calibration form.

5.4.4 To ensure completion of corrective and preventive action.

6.0 Distribution:

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Environment, Health and safety

7.0 PROCEDURE:

7.1 Calibration of Equipment/ instrument/measuring device

7.1.1 Concern responsible person of the department shall perform calibration of instrument or measuring device on the due date as per the procedure given in relevant SOP of the instrument / equipment/ device and record the data as per respective calibration format of that SOP.

7.1.2 The equipments or instruments or measuring devices which cannot be calibrated by in house procedure shall be identified by concerned department person & shall be calibrated by authorized external agencies & same shall be reviewed by engineering head and approved by QA head.

7.1.3 A calibration planner (Attachment-IV for in house calibration and Attachment-V for calibration by external agency) shall be prepared specifying the instrument/equipment/ measuring device name, its code no, calibration frequency, calibration done on, calibration due on etc.

7.1.4 In case of confirmed out of calibration situation, concern person shall make necessary entries in the instrument usage log and place a label for out of calibration as per SOP titled “Status Labeling” on the respective instrument/ equipment. They shall be taken out of the testing or manufacturing / testing program, as applicable.

7.1.5 Concern person shall immediately inform to Head of department for the further action.

7.2 Registration and issuance of out of calibration form.

7.2.1 The Head of department /designee shall review the calibration data.

7.2.2 Head of department/designee shall register the event in the "Out of calibration evaluation form issuance register" (Attachment-I) and issue an "Out of calibration evaluation form"(Attachment-II) to concern responsible person.

7.2.3 While issuance of the form Head of department/ designee shall make necessary entries in:

7.2.3.1 "Sr. No.", "Instrument/Equipment/ device Name"," Instrument/Equipment/Device ID no", "Form No.", "Date of Out of calibration", "Issued by/Date" columns of the Out of calibration evaluation form issuance register.

7.2.3.2 "Form No.", "Issued to", and "Issued by/Date", "Name of Instrument/equipment/device", "Instrument/ Equipment/Device ID no", "Calibrated by Sign/date" and "Description of failure" columns of the Out of calibration evaluation form.

7.3 Numbering of Out of calibration evaluation form

7.3.1 "Out of Calibration Evaluation form" can be numbered as "**OOC/YYYY-NNN**,

Where,

OOC= Stands for Out of calibration

YYYY= Stands for current year

NNN = Stands for serial number of out of calibration.

For example: First out of calibration of 2022 shall be OOC/2022-001.

7.4 Investigation of Out of calibration

7.4.1 Head of department/designee shall investigate the event as per, but not limited to, the Preliminary investigation check list given in the Out of calibration evaluation form and record the observations there in.

7.4.2 If cause of the failure is assignable,

7.4.2.1 Head of department/designee shall conclude it in the form and instruct same analyst (Analyst -1) to repeat the calibration of the instrument/equipment/device with same standard after rectifying the cause of the earlier failure.

Note: If failure is due to malfunction of the instrument/equipment/device then Head of department shall conclude accordingly in the form and hand over the form to Head QA or designee. Subsequently, Head QA or designee shall evaluate the impact of the failure as per 7.4.

7.4.2.2 Analyst shall record the raw data and observations in issued template and conclude the calibration along with the complete calibration report of that instrument/device.

7.4.2.3 Analyst shall intimate results to the Head of department/designee.

7.4.2.4 Head of department/designee shall enter the results in “Results/Observation” column of the form and conclude.

7.4.2.5 If calibration found satisfactory, Head of department/designee shall release the instrument/equipment/ device for use, after making necessary entries in “Remark(s)” of the form.

7.4.2.6 If Calibration found not satisfactory, Head of department/designee shall follow the procedure as per 7.3.3.

7.4.3 If cause of the failure is non assignable,

7.4.3.1 Head of department/ designee shall instruct another analyst (Analyst-2) to perform the calibration, taking fresh calibration standard.

7.4.3.2 Analyst shall record the raw data as per relevant SOP in calibration format and observations in issued template and conclude the calibration.

7.4.3.3 Analyst shall intimate results to the Head of department/designee.

7.4.3.4 Head of department/designee shall enter the results in “Results/Observation” column of the form and conclude.

7.4.3.5 If calibration found satisfactory,

7.4.3.5.1 Head of department/designee shall make necessary entries in “Head of department remarks” column of the form and instruct Analyst-2 to repeat the calibration after taking fresh calibration standard.

7.4.3.5.2 Head of department shall release the instrument/equipment/device for use, after making necessary entries in “Head of department remarks” column of the form. Head of department shall re-train Analyst-1, if require.

7.4.3.5.3 If Calibration is not satisfactory,

7.4.3.5.3.1 Head of department/designee shall make necessary entries in “Head of department/designee remarks(s) column of the form and conclude.

7.4.3.5.3.2 Head of department/designee shall hand over to Head QA or designee for further evaluation.

7.4.3.5.3.3 Head of department/designee shall intimate instrument/equipment engineer for rectification of the problem.

7.4.3.5.3.4 Head of department/designee shall evaluate impact of the failure as per the procedure given 7.4.

7.4.3.5.3.5 After rectification of the problem, Head of department/designee shall instruct Analyst-1 for calibration.

7.4.3.5.3.6 If any equipment/ instrument fails in calibration carried out by external agency or if any part of an instrument/ equipment shall be changed which may have major impact on instrument/equipment functioning then it shall be replaced/repaired. An investigation shall be done for the out of calibration according to the above mentioned procedure.

7.4.3.5.3.7 Impact of the failure on production & quality shall be done from the date of failure to previous date of calibration.

7.5 Impact Analysis.

7.5.1 Head of department/designee shall make a list of the samples analyzed between previous calibration and out of calibration duration time.

7.5.2 Head of department/designee shall select a product for reanalysis based on, but not limited to, the following criteria,

7.5.2.1 Last sample analyzed on the instrument.

7.5.2.2 The sample which was released at border to the specification.

7.5.2.3 The results are different than the previously reported results and non- complying to the standard specifications.

7.5.2.4 The results are different than the previously reported results but complying with the standard specifications.

7.5.3 Head of department/designee make necessary entries in “Sample requisition” column of the form and take authorization from Head QA or designee.

7.5.4 Head of department/designee Arrange for analysis of the selected samples on different instrument.

Note: In case of non-availability of another instrument, analysis can be done on same instrument after rectification of the problem and subsequent calibration.

7.5.5 Head of department/designee shall record the result of the original analysis and that of repeat analysis in the “Result(s)” of sample analysis columns of the form.

7.5.6 Head of department/designee shall conclude the investigation making note in the “Conclusion of impact analysis” and Head QA or designee remark(s)” columns of the form.

7.5.7 Head of department/designee shall recommend corrective and/or preventive action (s), if any, and forward the completed form to Head QA or designee for approval.

7.5.8 In case of manufacturing equipment showing out of calibration, Head QA or designee/Head Manufacturing and Head Maintenance shall jointly identify the critical quality attribute of the product that may get affected by the same.

7.5.9 The affected product shall be analyzed in QC and, if product fail incident shall be log as per incident SOP.

7.5.10 Repeated out of calibration incidences shall call for repairs or replacement of instrument.

7.5.11 Head QA or designee shall direct for further investigation, if require.

7.5.12 Head QA or designee shall decide further course of action in case of sample (s) failure.

7.5.13 Head QA or designee shall evaluate the investigation and approve the form.

7.6 Head QA or designee shall ensure completion of the recommended corrective / preventive action (s).

7.7 Head QA or designee shall ensure that the out of calibration evaluation form and supporting data are stored along with the calibration records.

7.8 OOC investigation shall be completed within 30 working days from the date of reporting of out of calibration result.

7.9 All relevant data of complete calibration report shall be attached with the investigation form of particular instrument / equipment/ device.

7.10 Follow the procedure as per flow chart (Attachment –III).

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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Attachment –I

Out of Calibration Evaluation Form Issuance Register

Sr. No.	Instrument /Equipment /device Name	Instrument/Equipment /device ID No.	Form No.	Date of Out of Calibration	Issued To	Issued by QA /Date	Received by /Date	Closed On	Remark

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Attachment-II

OUT OF CALIBRATION EVALUATION FORM

Form No.	**:**		**Name of Instrument/ Equipment/ device**	**:**	
Issued to	**:**		**Instrument/ Equipment/ device Code No.**	**:**	
Issued by QA Sign/ date	**:**		**Calibrated by Sign/ date**	**:**	

Description of Failure :

Preliminary Investigation

Sr. No.	Parameters	Observation	Sign/Date
1.	Status of calibration for other equipment(s)/Equipment used		
2.	Verification of calibration standards used **Primary standard :** • Physical appearance • Validity • Certificate **Secondary standard :** • Physical appearance • Validity		
3.	Verification of dilution, calculation, weighing, Titer values and readings.		
4.	Verification of glassware used		
5.	Verification of chromatograms/ spectra/ other instrument /equipment printouts etc.		
6.	Adequacy of system suitability checks		
7.	Instrument/ equipment Malfunction		
8.	Check for adherence to the calibration method		
9.	Discussion with analyst regarding his/ her understanding of the calibration methodology		
10.	Any other		

Conclusion : Cause assignable/Cause Non-assignable

Head of department remark(s) :

Head of department sign/ date :

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Re-calibration by Analyst –1/ Analyst –2

Result(s)/ Observation(s):

Name of analyst : **Date of calibration:**

Conclusion : Calibration Satisfactory/Calibration Not Satisfactory

Head of Department remark(s):

Head of department sign/ date:

Repeat calibration by Analyst –2

Result(s)/ Observation(s) :

Name of analyst : **Date of calibration:**

Conclusion : Calibration Satisfactory/Calibration Not Satisfactory

Head of department remark(s) :

Head of department sign/ date :

Instrument maintenance

Maintenance detail(s) :

Head of department remark(s) :

Head of Department(Sign/ Date) :

Impact analysis

Sample requisition

Sr. No.	Name of product	B. No./ A.R. No.	Quantity required	Selection criteria	Sample to be withdrawn from	Remark

Requested by sign/ date:
(Head of department)

Approved by sign/ date
(Head QA)

Result(s) of sample analysis :

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Sr. No.	Name of Product	B. No./ A.R No.	Test	Result of repeat analysis	Results of the original analysis	Limit

Conclusion of Impact analysis :

Head of department remark(s) :

Recommended Corrective/ Preventive Action(s), if any :

Head of department (Sign/ Date):

Head QA remark(s) :

Approved by Sign/ date:

(Head QA)

Attachment (s) if any____

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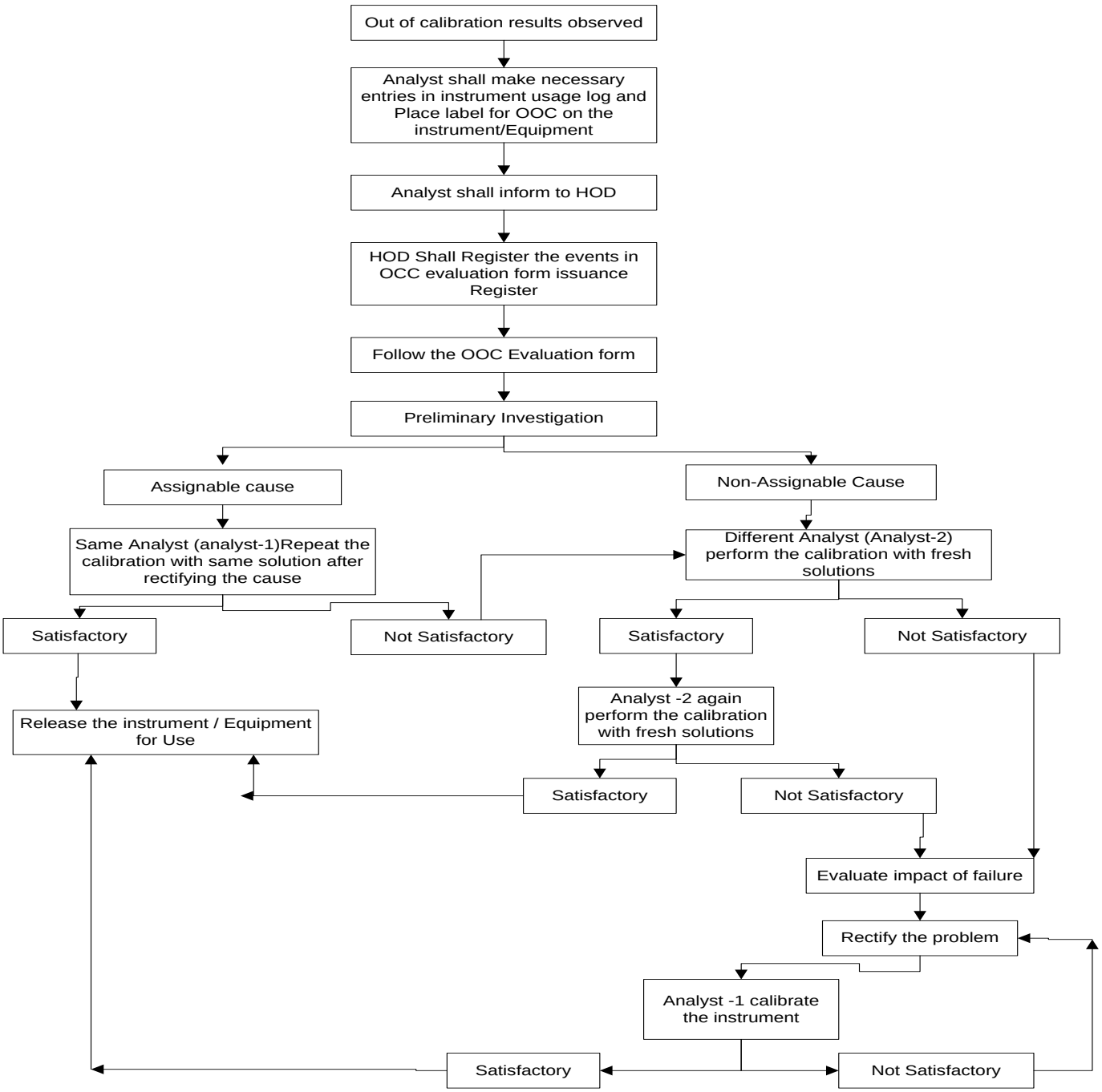
Attachment –III

Flow chart of OOC



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Attachment –IV

Master Calibration Schedule- In-house

Department:	**Year:**

Sr. No.	Instrument/ Equipment/ Measuring Device Name	Instrument/ Equipment/ Measuring Device Code No.	Calibration Frequency	Planned and Actual	Jan.	Feb.	Mar.	Apr.	May.	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
				P												
				A												
				P												
				A												
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				P												
				A												
				P												
				A												
				P												
				A												
				P												
				A												

P: Planned; A: Actual

Prepared by Department (Sign/ Date)	**Checked by Department Head (Sign/ Date)**	**Approved by QA Head (Sign/ Date)**

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Attachment –V

Master Calibration Schedule- External

Department:	**Year:**

Sr. No.	Instrument/ Equipment/ Measuring Device Name	Instrument/ Equipment/ Measuring Device Code No.	Calibration Frequency	Planned and Actual	Jan.	Feb.	Mar.	Apr.	May.	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
				P												
				A												
				P												
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				A												

P: Planned; A: Actual

Prepared by Department Person (Sign/ Date)	**Checked by Department Head (Sign/ Date)**	**Reviewed By Engineering Head (Sign/ Date)**	**Approved by QA Head (Sign/ Date)**