



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Calibration of Equipment and Instruments	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE

- 1.1 To lay down the procedure for calibration of equipments/instruments, wherever applicable.

2.0 SCOPE

- 2.1 This SOP is applicable for calibration of equipments /instruments at.....

3.0 RESPONSIBILITY

- 3.1 Personnel of the engineering department shall responsible to ensure and carry out all process equipment/instruments to be done as per schedule.
- 3.2 Personnel of the QC-instrumentation department shall responsible to ensure the calibration of all analytical equipment/ instrument to be done as per schedule.
- 3.3 Head of concerned department shall ensure the calibrations being performed or not as per the schedule.

4.0 ACCOUNTABILITY

- 4.1 Head - Engineering
- 4.2 Head - Quality Assurance

5.0 PROCEDURE

- 5.1 All the equipments/instruments associated with the processing and testing of materials and products shall be calibrated.
- 5.2 There shall be an SOP for calibration of each Equipment / Instrument which needs periodic in house / from certified out side agency traceable to NIST/ ETDC/NPL /In-House standards and any other applicable agency.
- 5.3 Calibration SOP of respective Instrument / Equipment shall contain the procedure of calibration, calibration frequency and acceptance criteria.
- 5.4 An annual calibration schedule shall be prepared by QC & Engineering personnel for equipments/instruments required to be calibrated by them/ concerned department/ outside agency as per Annexure-I.
- 5.5 The traceable of regular calibrations shall be followed as per their frequency and the due date in calibration schedule.



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- 5.6 The calibration schedule consists of the Instrument ID and its location/equipment connected, Next due of calibration. After performing the calibration within the grace period from its due date, the date of calibration shall be entered in the schedule with sign.
- 5.7 The calibration data shall be entered in the calibration certificate .The calibration certificate shall contain the details of Instrument under calibration, details of the master used, Calibrated done on, Next calibration due on, calibration raw data etc. Second authorized person shall verify the calibration certificate.
- 5.8 Calibration shall be carried out within ± 2 days for quarterly, within ± 5 days for half yearly & ± 10 days for annual calibrations from the due date. The instruments having daily and monthly calibration schedules should calibrate on the due date itself.
- 5.9 If the calibration due date of monthly calibrated instruments is held on holiday, then the calibration shall be done on the previous day.
- 5.10 If there is continuous production even in the total grace period from the calibration due date of equipment/instrument. Then the calibration activity shall be performed immediately after completion of production or if any deviation is observed in the instrument related to that equipment/area which is in continuous production.
- 5.11 Before starting the calibration activity, the same shall be intimated to the concerned user department personnel for clearance.
- 5.12 During calibration tag the instrument /equipment with Under Calibration label filled as per Annexure – IV.
- 5.13 If the Equipments / Instruments pass the calibration test, put “CALIBRATED” label duly filled as per Annexure – V.
- 5.14 If the Equipments / Instruments fails in calibration test put “CALIBRATION FAILED” label duly filled as per Annexure – VI, and the equipment/Instrument shall not be used till the instrument repaired or replaced and calibrated.
- 5.15 If any Equipments / Instruments fail the calibration, failure shall be investigated by the in charge of QA & head of concerned department. The reason for failure and the effects of failure on quality of product since last calibrated shall be covered during investigation and appropriate action is taken.
- 5.16 In case of the calibration is performed due to a break down repair, change of parts or for any other reason before the next schedule date of calibration the same shall be recorded in the respective calibration record.
- 5.17 The scheduled date of calibration shall not be disturbed due to any calibration performed before the schedule date of calibration.
- 5.18 Incase of new equipment /instrument installation, the calibration schedule of new equipment/instrument shall be updated for every three months with separate Annual schedule sheet adding to the existing schedule.



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- 5.19 A History Record shall be maintained for each equipment/ instrument as per the Annexure – II in which details of the particular equipment / instrument, successive calibrations and their results shall be recorded.
- 5.20 In case an external agency has calibrated the equipment, the calibration certificate shall be signed with authorized persons from QA and Engineering/ QC personnel as a mark of acceptance.
- 5.21 If any master instrument is used for internal calibration/Validation, the details of the person received and date of its using is entered in the Master Instrument User Log as per the Annexure - III.
- 5.22 The Master Instrument User Log shall also contain the details of Equipment / Area of using the master instrument.

6.0 ABBREVIATIONS

- 6.1 NIST– National Institute of Standard Tests.
- 6.2 NPL– National Physical Laboratories.
- 6.3 ETDC– Electronic Test and Development Centre.
- 6.4 QA- Quality Assurance
- 6.5 QC- Quality Control
- 6.6 SOP- Standard Operating Procedure

7.0 ANNEXURES

- 7.1 Annexure - I Annual Equipment / Instruments Calibration Schedule
- 7.2 Annexure - II Instrument History Record.
- 7.3 Annexure - III Master Instrument User Log.
- 7.4 Annexure - IV Under calibration label.
- 7.5 Annexure - V Calibrated label.
- 7.6 Annexure - VI Calibration Failed label.

CHANGE HISTORY		
Supersedes SOP No.	Change Control No.	Changes made
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ANNEXURE-1

ANNUAL CALIBRATION SCHEDULE OF CONTROL INSTRUMENTS / GAUGES FOR THE YEAR OF

S.No.	Instr. Name	ID No.	Equip./Location	Equip No.	MONTH											
					Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
The calibrations shall be carried out within +/- 5 days from the due date for Half-Yearly & +/- 10 days for Annually.																
Note: Each Month block of the Instrument is divided into 2 parts, in which the scheduled due date is entered in upper part. In the Lower part of the block, the calibration done date shall be entered with sign.																
PREPARED BY (ENGG)				CHECKED BY (ENGG)									APPROVED BY (QA)			



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ANNEXURE-II

INSTRUMENT HISTORY CARD

Name of the Instrument:					Area:	
Instrument Identification No.					Location/Equipment:	
Range:					Date of Installed:	
Make:					Frequency of calibration:	
Resolution:					Type of Input applied:	
Size of the Instrument:						
Accuracy/Acceptance Criteria:						
Details of Calibration						
S.No.	Date of Calibration	Due date	Cycle No.	With in Accuracy (YES/NO)	Physical Condition (OK/NOT OK)	Remarks
1						
2						
3						
4						
5						



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ANNEXURE IV

UNDER CALIBRATION

Name of the Instrument:-----

Identification No. :-----

Location:-----

Date: ----- Signature:-----

Format No:



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ANNEXURE V

CALIBRATED LABEL

Name of the Instrument:-----
Identification No. :-----
Location:-----
Calibration Date:----- Due Date:-----
Done By:----- Checked By:-----
Date:----- Date:-----
Format No:



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ANNEXURE - VI

CALIBRATION FAILED LABEL

Name of the Instrument:-----
Identification No. :-----
Location:-----
Date: ----- Signature:-----
Format No: