



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Calibration of measuring Instruments/Devices/Equipments	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down procedure for initiation of calibration and vendor selection for calibration of all measuring Instruments / Devices / Equipments.

2.0 SCOPE:

This procedure is applicable to all measuring instruments / devices / equipments installed.

3.0 RESPONSIBILITY:

3.1 Associate officer and above of Engineering dept. and QA dept shall be responsible for the initiation and verification of calibration execution activity.

3.2 Associate officer and above of QA dept shall be responsible for the maintenance of the list of measuring devices and coordinate with external agency.

3.3 Executive and above of QA dept. shall be responsible for verification of calibration activity as per the CMP and maintaining the calibration certificates / reports provided by vendor.

4.0 ACCOUNTABILITY:

Head QA

5.0 PROCEDURE:

5.1 All measuring devices except analytical instruments shall be calibrated by external party.

5.2 User dept. shall identify and will prepare a list of measuring instruments / equipments required to calibrate and will submit the same to QA.

5.3 QA department shall identify all the measuring instruments / equipments in **Critical** and **Non - critical** instruments respectively on the basis of their criticality of measurement and impact of the measured reading on product quality

5.4 QA department shall define the frequency of calibration of measuring instruments as per following with respect to criticality criteria:

5.4.1 **Critical instruments** – Six Monthly

5.4.2 **Non – critical instruments** – Yearly.



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- 5.5 QA Dept. shall maintain the list of all measuring instruments / equipments, department wise and provide the list to external agency.
- 5.6 External calibration agency should be decided with the help of purchase department and shall be audited once in a year.
- 5.7 The external party should have an annual calibration agreement/ contract duly signed by both the parties along with the rate list attached.
- 5.8 The written calibration agreement/ contract will be applicable for a period of one year of the respective financial year.
- 5.9 It is mandatory for the external party to provide the certificate of master instrument duly certified by NABL or Govt. of India.
- 5.10 During calibration, site representative from Engineering and QA dept shall witness the calibration execution activity as per the SOP's submitted by the external agency.
- 5.11 The external calibration agency will affix the calibration tags on the calibrated instrument / equipment having the following details:
- Certificate No. :
Instrument Name :
Instrument ID / Tag No.:
Location :
Calibration date :
Calibration due date :
Calibration Done By :
- 5.12 After calibration the External calibration Agency shall submit the Calibration Report and Calibration certificates for individual calibrated instrument in specified format.
- 5.13 The external calibration agency will submit the traceability certificates of the master calibrators from NABL or Govt. of India certified lab.



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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6.0 REFERENCE:

Document No.	Title
CMP/00	Calibration Master Plan

7.0 ANNEXURE:

Not Applicable

8.0 ABBREVIATION

SOP : Standard Operating Procedure

No. : Number

Dept. : Department

CMP : Calibration Master Plan

NABL : National Accreditation Board for Testing and Calibration

QA : Quality Assurance