



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Preparation of Calibration schedule of Instruments Calibration Practice	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

#### 1.0 OBJECTIVE:

To lay down procedure for preparation of Calibration schedule of Instrument and Calibration practices.

#### 2.0 SCOPE:

This SOP is applicable to Chemical lab.

#### 3.0 RESPONSIBILITY – Execution - Executive QC.

Checked by - Assistant Manager QC

#### 4.0 ACCOUNTABILITY - Manager Quality Control

#### 5.0 PROCEDURE:

##### 5.1 Calibration Schedule Preparation

5.1.1 Calibration schedule should be prepared by calibration coordinator or designee for all the instruments, which are applicable.

5.1.2 Calibration schedule should contain “ Sr.No.” “ Instrument Name”, “ Code No.”, “Frequency”, “Tolerance”, “Calibration due on “, “ Sign/Date”, “ History” (History shall contain column of “ date”, “ history details”, “ Name of instrument”, “ Code No.”, “Done By/Date” and “ approved by/ date” ) and duly sign by calibration coordinator (Annexure-III). Designated person shall verify and make tick mark on the “ frequency” “Tolerance”, and on “Calibration due on”.

5.1.3 Frequency and tolerance shall be kept as per the respective instrument SOP.

5.1.4 Calibration of the performance duration and tolerance shall be considered as per following or as per the respective SOP.

15days ± 2days

30days(Monthly) ± 3days

60days(Bi-monthly) ±6days

90days(Quarterly) ± 7days

120days(6 Monthly) ± 15days

365days(Yearly) ± 30days

5.1.5 Coordinator shall update the schedule in case of calibration frequency change of the instrument and mention in the “ Remark” column of calibration schedule and prepare new schedule and attached with the main calibration schedule.

5.1.6 If new instrument is purchased then calibration coordinator shall update the calibration schedule and instrument master list. The identification of new instrument shall be done



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as per SOP.

5.1.7 Calibration due date for the next calibration shall be decided based on the last calibration performed date.

#### 5.2 Calibration Practices

5.2.1 Calibration coordinator shall prepare the calibration format for all instrument as per Respective instrument SOP and calibration format shall contain columns of "Title", Reference SOP

5.2.2 Calibration format issuance register shall contain column of "Issuance No.", "Name of calibration format", "Instrument Code No.", "Issued to", "Issued on", and "Issued by" Annexure-I)

5.2.3 Calibration coordinator shall issue the calibration format when instrument is required and put the stamp of "Issuance No.", "Issued by" and "date".

5.2.4 Entry shall make in the calibration format issuance register for "Issuance No.", Name of calibration format", "Instrument code No." "Issued To", "Issued on", and "Issued by"

Issuance No. shall be allotted as "XXX/YYYYY".

Where,

"XXX" is stands for serial no. of format issued in the respective year.

"YYYYY" is stands for year.

5.2.5 Calibration coordinator /analyst shall follow the procedure of respective instrument SOP for the calibration.

5.2.6 If calibration is found out of calibration then immediately inform to Manager QC or designee and follow the SOP on "Handling of out of calibration results".

5.2.7 After completion of calibration, raw data shall be submitted for the review to designated person.

5.2.8 After satisfactory calibration, calibration coordinator shall update the status label of the calibration as per Annexure-II.

5.2.9 If instrument is not calibrated within tolerance days due to the instrument maintenance /shifting then make a note in the "History" of the calibration schedule an same entry shall be made in the instrument history card.

5.2.10 If usage of instrument is discontinued then make a note in the "History" column of the calibration schedule and mention "Na" in the column of "Sign/date" of the calibration schedule Same entry shall be made in the instrument history card as per SOP on "Maintenance of laboratory instrument"

5.2.11 In case of the new instrument of the same model /make then current SOP can be referred for



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6.0 **SAFETY & PRECAUTIONS:**  
operation and calibration.  
Not Applicable

7.0 **REVISION HISTORY:**

Revision No.	Reason for Revision	Superseded from & Date

8.0 **DISTRIBUTION:**

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/Date	By	Sign/Date

9.0 **REFERENCES:**  
SOP "Allocation of identification number to instruments/equipments"

10.0 **ABBREVIATIONS & ANNEXURES:**  
SOP : Standard Operating Procedure  
QC : Quality Control

**Annexure I** : Calibration format issuance register

**Annexure II** : Format Of Instrument Master List

**Annexure III** : Format Of Calibration Schedule







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### ANNEXURE III

#### FORMAT OF CALIBRATION SCHEDULE

#### CALIBRATION SCHEDULE FOR 20XX-20XX (QUALITY CONTROL)

S.No.	Instrument	Code no.	Frequency	Tolerance	CALIBRATION DUE ON

To be mentioned last two digit of the year.

**Prepared by :**

**Checked by:**

**History:**

S.No.	Date	History details	Name of instrument	Code No.	Done by / date	Approved by / date