



# PHARMA DEVILS

## ENGINEERING DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Engineering	<b>SOP No.:</b>
<b>Title:</b> Procedure for Calibration of field instruments	<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 the Procedure for Calibration of field instruments.

#### 2.0 SCOPE:

This standard operating procedure (SOP) is applicable for calibration of field instruments.

#### 3.0 RESPONSIBILITY:

Executive Engineering will perform the Calibration and prepare the data sheet.

Manager Engineering will check the data sheet and calibration certificate.

Manager QA will verify & approved the data and calibration certificate

#### 4.0 PROCEDURE:

- 4.1 Ensure that Master Instruments used for calibration are in calibration state before starting the calibration.  
Executive engineering shall prepare the Annual Calibration Plan for succeeding year for all equipment/instruments as per Annexure-1 in the month of December.
- 4.2 Manager Engineering shall check prepared plan and same shall be submitted to Manager QA for their approval.
- 4.3 Executive Engineering shall prepare the list of instrument to be calibrated in each month, on the last week of each month as per annexure-II
- 4.4 Executive Engineering shall inform to concern department supervisor for calibration of instruments in advance
- 4.5 Executive Engineering shall perform the calibration of instrument as per their respective SOP.
- 4.6 Executive Engineering shall record the observation in the respective data sheet and it shall be submitted to Manager Engineering for his review.
- 4.7 QA shall verify the data sheet and approved the calibration certificate..
- 4.8 Calibration Certificate No. Shall be given as follows:  
DD/PMN/ID  
DD: Date of Calibration.  
PMN: Promed Manufacturing Nalagarh.  
ID: Instrument Identification Number.  
For Example: Calibration certificate number of pressure gauge having ID U/012-PG 01 performed on 12.04.07 as under.  
12.04.07/PMN/U/012-PG 01.
- 4.9 After re-calibration retrieves the old tag and destroys. Record the details as per Annexure -III
- 4.10 Verify each instrument for ID No. Affx the tag and compile the details as per annexure IV
- 4.11 If the calibration results not meet the acceptance criteria then replace it with new equipment/instrument and maintain the record as per Annexure-V
- 4.12 Before installing the instrument recalibrate it as per respective SOP and inform the QA Department after the installation.



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#### 4.3 FREQUENCY:

- 4.3.1 Direct impact to the manufacturing process six monthly.
- 4.3.2 Indirect impact to the manufacturing process yearly.

#### 4.4 TOLERANCE LIMIT:

- 4.4.1 +/- 7 Days in case of six monthly
- 4.4.2 +/- 15 Days in case of yearly.

#### 5.0 SAFETY AND PRECAUTIONS:

Not Applicable

#### 6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date
00	New	-----

#### 7.0 REFERENCES:

Not Applicable

#### 8.0 ABBREVIATIONS:

SOP: Standard Operating Procedure.  
ID: Identification Number  
QA: Quality Assurance

#### 9.0 ANNEXURE:

Annexure – I: Annual calibration plan  
Annexure – II: Next month Calibration plan  
Annexure – III: Old calibration tag record  
Annexure – IV: Calibration tag  
Annexure – V: Instrument replacement record



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#### Annexure – I Annual calibration plan

Equipment Name	Name of Instrument	ID.No	Jan		Feb		Mar		.....	Dec	
			P	A	P	A	P	A		P	A

P: Plan Column: Fill the date and make it yellow for six monthly calibration and Light green for Yearly calibration.

A: Actual Column: Fill the actual date of calibration and make it Green.







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#### Annexure IV Calibration Tag

	SOP REF. No.:
<b>CALIBRATED</b>	
INSTRUMENT NAME	
INSTRUMENT ID.	
LOCATION	
CERTIFICATE NO.	
CALIBRATION ON	
NEXT DUE ON	
CALIBRATED BY	CHECKED BY

