



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Calibration of pH Meter

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 5	

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Calibration of pH Meter.

2.0 SCOPE:

This SOP is applicable for Operation and Calibration of pH Meter used in Production department.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATION:

°C	degree Celsius
KCl	Potassium Chloride
Ltd.	Limited
M	Molarity
ml	Milliliter
pH	Power of Hydrogen ions (-ve log of hydrogen ions)
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1 Check and ensure that the instrument is clean.
- 6.1.2 Check the due date of Calibration if it is within date then use otherwise first calibrate then operate.
- 6.1.3 Switch "ON" the mains then press the switch "ON/OFF" of the pH meter.
- 6.1.4 Remove the glass electrode from 0.3 M KCL (Saturated Potassium chloride solution), wash thoroughly with cool WFI and wipe with tissue paper.
- 6.1.5 Press the pH menu from "Mode" switch of pH meter.
- 6.1.6 Dip the glass electrode in the beaker containing test solution/suspension.
- 6.1.7 Wait till the reading of pH of solution stabilized and screen of pH meter displayed stable pH of the solution, without any fluctuation in pH reading.
- 6.1.8 Press the switch of "HOLD" and note the reading in the respective record.
- 6.1.9 Record the details in format "**pH Meter Operation and Usage Log**" in Annexure –I.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Calibration of pH Meter

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 5

6.1.10 Rinse the pH glass electrode and Temperature probe 2-3 times with cool WFI water and wipe dry with tissue paper.

6.1.11 Dip the glass electrode in 0.3 M KCL when not in use.

6.2 CALIBRATION:

6.2.1 Put pH electrode in 4.01 buffer and go to mode key, as soon as the instrument starts to show pH of the buffer, **press CAL key**, the instrument will display previous calibration data (if stored Earlier) or otherwise it will show “**No Data**”.

6.2.2 Press enter key and the display will show **BUF1**=put value 4.01 in display by numeric keys, as soon as the value gets stable, press **Enter** key, the instrument will now Show **BUF2**=.

6.2.3 Rinse the pH glass electrode and Temperature probe 2-3 times with purified water and wipe with dry tissue paper.

6.2.4 Follow same process for 6.87 & 9.18 buffer solution.

6.2.5 After calibration with 9.18 buffers the instrument will show calibration over and electrode slope will be stored in memory of the instrument. Limit of the slope of calibration will be from 90% to 110%. If the slope is within limits, display will read satisfactory, and then your instrument is ready for pH measurement.

6.2.6 If calibration had done successfully then, display show Calibration Over, Otherwise. Display show “Incorrect buffer probe faulty”.

6.2.7 Remove the pH Electrode and Temperature Probe from buffer and rinse with Purified Water, wipe dry with tissue paper.

6.2.8 Dip the glass electrode 0.3 M KCL solution.

6.2.9 Check the Electrode internal reference filling solution level, if necessary levels it with recommended solution (0.3M KCL).

6.2.10 Prepare Solution weekly/arrange from QC on weekly basis or when required.

6.2.11 Record the observation in **Annexure - I**.

6.2.12 Verification of pH Meter: Insert the pH Electrode and Temperature Probe in a solution of 4.01, 6.87 & 9.18 pH buffer and verifying the same solution. Wait until stabilized reading and record the observation.

6.2.13 Remove the pH Electrode and Temperature Probe and rinse with Purified Water.

6.2.14 Wipe the electrode with Tissue Paper without touching the Bulb of pH Sensor.

6.2.15 Dip the electrode in saturated potassium chloride (0.3 M KCL) solution at rest.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Calibration of pH Meter

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 5

6.2.16 All the observations shall be recorded in format “**Calibration Record of pH Meter**” as shown in **Annexure-II**.

6.2.17 Acceptance criteria/ Tolerance Limit: **pH ± 0.02** of Standard buffer solution.

6.2.18 All the measurement shall be carried out at temperature **25±2°C**.

6.2.19 Rinse the electrode each time with WFI and wipe dry with tissue paper to dry.

6.2.20 If Calibration not found satisfactory i.e. all result not come within Acceptance criteria during calibration, inform to Head of Department and affix ‘Out of Order’ label on the Instrument.

6.2.21 FREQUENCY: Before pH measurement/ whenever required.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	pH meter operation and usage log	
Annexure-II	Calibration record of pH meter	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

In House

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change control No.	Details of Changes	Reason for Change	Effective Date	Prepared By



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Calibration of pH Meter

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	5 of 5	

ANNEXURE – II CALIBRATION RECORD OF pH METER

Instrument ID:

Date	pH of Buffer Solution	Observed Value	Pass/ Fail	Due Date	Done By Sign & Date	Checked By Sign & Date	Remark

Frequency: Weekly or Whenever Required.

Temperature of the solution in $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$