



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Calibration/Verification of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Operation and Calibration/Verification of pH Meter.

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATION:

°C	degree Celsius
KCl	Potassium Chloride
Ltd.	Limited
M	Molarity
ml	Milliliter
pH	Potential of Hydrogen
Pvt.	Private
QA	Quality Assurance
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.
- 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 purified water and wipe with tissue paper.
- 6.1.5 Press the "Cal/Meas" switch and insure that the display of pH meter shows "Meas".
- 6.1.6 Dip the glass electrode and in the beaker containing test sample.
- 6.1.7 Wait till the reading of pH of test sample stabilized and screen of pH meter displayed "READY".
- 6.1.8 Press the switch of "HOLD" and note the reading in the respective record "**pH Meter Operation and Calibration/ Verification Log**" as shown in **Annexure -I**.



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

6.1.10 Dip the glass electrode in 0.3 M KCl when not in use.

6.2 Calibration:

6.2.1 Store buffer solution in dedicated bottles and use within one week from date of preparation from Quality control department.

6.2.2 Buffer solution containing any suspended particles should be discarded.

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

6.2.4 Press the “Cal/Meas” switch and ensure that the display of pH meter shows “Cal”.

6.2.5 Pour one by one 30 ml (approx.) buffer solutions quantity having pH of 6.87, 4.01 & 9.18 into different status marked beakers for pH solution to perform the calibration of pH meter and ensure the pH electrode emerged inside the pH solution. Wait till the pH ready shows ready. Then record the reading showing on displayed against the reference buffer solution 6.87, 4.01 and 9.18.

6.2.6 Dip the glass electrode in pH 6.87 buffer solution in a beaker and stir gently.

6.2.7 Wait till the reading of pH of buffer solution stabilized and screen of pH meter displayed “READY”. Then press the switch “ENTER”, wait the reading to be stable.

6.2.8 Remove glass electrode from the buffer & rinse with purified water to make it free of buffer, wipe dry with tissue paper.

6.2.9 Then repeat the same by Dipping the glass electrode in pH 4.01 buffer solution in a beaker and stir gently.

6.2.10 Wait till the reading of pH of buffer solution stabilized and screen of pH meter displayed “READY”. Then press the switch “ENTER”, wait the reading to be stable.

6.2.11 Remove glass electrode from the buffer & rinse with purified water to make it free of buffer, wipe dry with tissue paper.

6.2.12 Dip the glass electrode in pH 9.18 buffer solution in a beaker and stir gently.

6.2.13 Wait till the reading of pH of buffer solution stabilized and screen of pH meter displayed “READY”. Then press the switch “ENTER”, wait the reading to be stable.



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6.2.14 Remove glass electrode from the buffer & rinse with purified water to make it free of buffer, wipe dry with tissue paper.

6.2.15 All the observations shall be recorded in format “**pH Meter Operation and Calibration/ Verification Log**” as shown in **Annexure-I**.

6.2.16 Acceptance criteria / Tolerance Limit: $\text{pH} \pm 0.05$ of Standard buffer solution.

6.2.17 All the measurement shall be carried out at temperature $25 \pm 2^\circ\text{C}$.

6.2.18 Rinse the electrode each time with purified water and wipe dry with tissue paper to dry.

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

6.2.20 FREQUENCY OF CALIBRATION: Every fortnight or after any maintenance work.

6.3 Verification:

6.3.1 Verification of pH meter to be done on daily basis after the start of the instrument.

6.3.2 Verification of pH meter to be done with the reference standards of buffer solutions 6.87, 4.01 & 9.18 pH solutions.

6.3.3 Remove glass electrode from the buffer & rinse with purified water to make it free of buffer, wipe dry with tissue paper.

6.3.4 Dip the glass electrode in 30 ml pH 6.87 buffer solution in a beaker and stir gently.

6.3.5 Wait till the reading of pH of buffer solution stabilized and screen of pH meter displayed “READY”. Then press the switch “ENTER”, wait the reading to be stable then record the observation.

6.3.6 Repeat the same process with buffer solution 4.01 and 9.18 and record the observation on log book **pH Meter Operation and Calibration/Verification Log**” as shown in **Annexure-I**.

6.3.7 Remove glass electrode from the buffer & rinse with purified water to make it free of buffer, wipe dry with tissue paper and dip the electrode in 0.3M KCL solution after verification completed.



PHARMA DEVILS

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6.3.8 If Verification not found satisfactory i.e. all result are not coming within Acceptance criteria during verification (Acceptance criteria / Tolerance Limit: $\text{pH} \pm 0.05$) then calibration to be performed.

6.3.9 FREQUENCY OF VERIFICATION: Daily or after any maintenance work.

6.3.10 Frequency of Buffer Preparation & Label on Buffer Bottles:

Buffer solution shall be change / prepare and labeled on weekly basis or whenever required.
Affix the label on bottles of buffer solution as per QC format.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	pH meter operation and calibration/verification log	

ENCLOSURE: 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	Updated By



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ANNEXURE -I
pH METER OPERATION AND CALIBRATION/VERIFICATION LOG

Instrument ID. No. :

Date	Product Name	Batch No. / pH of Buffer Solution	Start Time	End Time	Observed value	Done By Sign & Date	Checked By Sign & Date	Remarks

Frequency of Calibration Fortnight or Whenever Required.

Frequency of Verification Daily or Whenever Required.

Acceptance criteria / Tolerance Limit: pH \pm 0.05