



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Operation & Cleaning of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Operation and Calibration of pH meter.

2.0 SCOPE:

2.1 This SOP is applicable for pH meter MAKE: LAB INDIA, MODEL: PICO+ in production (Liquid orals).

3.0 RESPONSIBILITY:

3.1 Officer / Executive Production, IPQA: Performing the in-process checks during manufacturing

3.2 Head Production: Ensure the in-process checks

4.0 DEFINITION:

4.1 pH: It is negative logarithm of hydrogen ion concentration of water.

5.0 PROCEDURE:

5.1 OPERATION:

5.1.1 Ensure that instrument is clean and free from dust.

5.1.2 Ensure the calibration status of the instrument.

5.1.3 Lift the electrode holding clamp at appropriate height by moving up and down, wash the electrode and the temperature sensor with purified water, keep the wash water in a beaker and dry the electrode and the temperature sensor with the help of dry lint free duster.

5.1.4 Switch 'ON' the mains and switch ON the instrument provided on back side of the instrument (if required).

5.1.5 Put the electrode into the sample and wait till a Stable pH reading is displayed. The value of pH will be displayed on the display board and note down the reading.

5.1.6 Remove the sample solution, rinse the electrode with purified water and keep the wash water in a beaker and dry with dry lint free duster and dip the electrode into the pH 4.01 buffer solution.

5.1.7 Discard the liquid after checking the pH in wash area by adding sufficient quantity of water.

5.2. CALIBRATION PROCEDURE



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Operation & Cleaning of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.1 Use following range of pH for calibration for 3 Point calibration.
1. pH 4.01 2. pH 6.86 3. pH 9.18
- 5.2.2 Press MODE key followed by ENTER key, wait for few seconds some pH value will be displayed on the display board.
- 5.2.3 Press MEM CLEAR key, enter password will be displayed.
- 5.2.4 Type password 'XXXX' then press ENTER. For password refer reference SOP ("Procedure for password protection of PLC system").
- 5.2.5 To clear all memory contents, reading as well as calibration data, press 3 (ALL) and then ENTER. Entire Memory will be cleared and display will show 'memory is cleared'.
- 5.2.6 Press CAL key 'NO DATA' will display then press enter password will be displayed.
- 5.2.7 Type password 'XXXX' then press ENTER.
- 5.2.8 Display will show, 'calibration mode: **1) stand 2) calib.**
- 5.2.9 Select '1' and then press ENTER display will be '**use (Buffer 6.8 -7.2)**'.
- 5.2.10 Remove the electrode from the buffer solution and rinse the electrode with purified water, keep the wash water in a beaker, wipe and dry the electrode and sensor with dry lint free duster.
- 5.2.11 Take the buffer of pH 6.86 and dip the electrode in buffer pH 6.86 and type 6.86 value then press ENTER, wait for few seconds, display will show pH value ,wait for stabilize the value.
- 5.2.12 Instrument will display the value of buffer pH 6.86 The value should be between ± 0.1 . (Limit - 6.760 – 6.960). Record the displayed value on Annexure-I (Calibration Record of pH meter).
- 5.2.13 Press ENTER, display will show '**calibration 1) Y, 2) N**'
- 5.2.14 Remove the electrode from the previously used buffer solution and rinse the electrode with purified water, wipe and dry the electrode and sensor with dry lint free duster.
- 5.2.15 Select 1 (Y), and then press ENTER, display will show **Buffer < 6.5**
- 5.2.16 Take the buffer of pH 4.01 and dip the electrode in buffer pH 4.01 and type 4.01 value then press ENTER, wait for few seconds, display will show pH value, wait for stabilize the value.
- 5.2.17 Instrument will display the value of buffer pH 4.01.The value should between ± 0.1 i.e (3.910 – 4.110). Record the displayed value on Annexure-I (Calibration Record of pH meter).



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Operation & Cleaning of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.18 Press ENTER, display will show '**calibration 1) Y, 2) N**'
- 5.2.19 Remove the electrode from the previously used buffer solution and rinse the electrode with purified water, wipe and dry the electrode and sensor with dry lint free duster.
- 5.2.20 Select 1 (Y), and then press ENTER, display will be **Buffer > 7.5**
- 5.2.21 Take the buffer of pH 9.18 and dip the electrode in buffer pH 9.18 and type 9.18 value then press ENTER, wait for few seconds, display will show pH value. Wait for stabilize the value.
- 5.2.22 Instrument will display the value of buffer pH 9.18. The value should between ± 0.1 i.e. (9.080 – 9.280). Record the displayed value on Annexure-I (Calibration Record of pH meter).
- 5.2.23 Press ENTER, instrument will display "**Calibration is over**".
- 5.2.24 Remove the electrode from the previously used buffer solution and rinse the electrode with purified water, wipe and dry with dry lint free duster.
- 5.2.25 Dip the electrode in pH 4.01 buffer solution.
- 5.2.26 After completion of calibration press MODE key and select pH mode.

5.3 Calibration Frequency

- 5.3.1 Every day.

NOTE :

1. Take Approximately 20 ml (Volume is depending upon the size of beaker used for calibration) of standard buffer solution from original stock for daily calibration. Discard the 6.86 & 9.18 buffer solution after use. Use 4.01 buffer solutions for electrode dipping. Make the record as per Annexure-II {"Buffer solution usage record"}.

2. The opened original bottle of buffer solution shall be used with in one month and labeled as per Annexure-III {"pH buffer dispensed label"}

3. Buffer details like Batch No. and Exp. Date etc shall be taken from the COA of the buffer

- 5.3.2 Fill the calibration status on calibration status label of the instrument.
- 5.3.3 If instrument is out of calibration, affix "OUT OF CALIBRATION" label and handle the situation as per SOP ("Handling of Out of Calibration").

5.4 CLEANING

- 5.4.1 Clean the instrument daily with dry lint free cloth, Occasionally use clean wet cloth. Immediately followed by clean dry lint free cloth.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Operation & Cleaning of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4.2 Rinse the pH electrode with excess of purified water before and after every use and dry the electrode with lint free duster.

5.5 PRECAUTIONS

5.5.1 Handle electrode with care.

6.0 ABBREVIATION (S):

6.1 IPQA : In-process Quality Assurance.

6.2 QA : Quality Assurance.

6.3 COA : Certificate of Analysis.

6.4 NLT : Not less than

7.0 REFERENCE (S):

7.1 SOP: Procedure for password protection of PLC system.

7.2 SOP: Handling of Out of Calibration.

7.3 SOP: Operation and Calibration of pH meter.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure – I	Calibration Record of pH meter		Logbook
Annexure – II	Buffer solution usage record		Logbook
Annexure – III	pH buffer dispensed label.		Label

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (S):** Production (01), Quality Assurance (01)

9.3 **Reference Copy (S):** Production (01)

10.0 REVISION HISTORY:

S. No.	Revision No.	Change Control No.	Reason (s) for revision	Details of revision	Revision Date



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Operation & Cleaning of pH Meter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE III pH Buffer Dispense Label

Name of Buffer	:
Batch No.	:
Expiry Date	:
Open on	:
Use Before	:
Sign	:
Date	:
Format No.	