

PHARMA DEVILS QUALITY CONTROL DEPARTMENT

This SOP is applicable for Operation & Calibration of pH meter in the Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive -Quality Control Department. Head - Quality Control Department

4.0 **DEFINITION(S):**

pH: It is the negative logarithm to the base 10 of hydrogen ion concentration.

5.0 **PROCEDURE:**

Make: Lab India , Model: Pico+

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 Switch on the mains and Switch on the power button of the instrument.
- 5.1.4 Lift electrode holding clamp at the appropriate height on the rod of the electrode stand and wash the electrode with purified water, wipe and dry with tissue paper.
- 5.1.5 After switch on the pH Meter, only two Key active i.e. Reset and Mode. Reset Key is used to initialization and mode Key is used to particular selection of operation.
- 5.1.6 Press Mode Key and Select pH Mode by ENTER Key.
- 5.1.7 Wait for 30 seconds or till Stability of pH reading. The value of pH of sample will be display on the Screen and note the reading.
- 5.1.8 Remove the sample solution, rinse the electrode with purified water and wipe with tissue paper and dip the electrode in 7.0 pH Buffer saturated with KCl or 3M KCl Solution.
- 5.1.9 Note down the operation activity in the instrument log book.



PHARMA DEVILS QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Control	SOP No.:		
Title: Operation and Calibration of pH meter	Effective Date:		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

5.2 Calibration:

- 5.2.1 Operate the instrument as mention in the above procedure.
- 5.2.2 Prepare the buffer pH 4.0, pH 7.0 and pH 9.2 solution by dissolving 10 tablets / capsules of standard buffer in 1000 ml volumetric flask with purified water respectively.
- 5.2.3 Press mode key and select pH mode by ENTER. Press CAL key for instrument calibration. Instrument ask password, give 1234 and press ENTER. Instrument ask for calibration mode 1)
 Stand. 2) Calib. Perform the Standardization first with 7.0 pH buffer and then calibrate with 4.0 pH buffer and 9.2 pH buffer.

Select Stand. Mode and press ENTER. Instrument ask for buffer (6.8-7.2)

- 5.2.4 Dip the electrode in buffer pH 7.0 solutions and press ENTER. Instrument ask for calibration
 1) Y, 2) N. Select 1 and press ENTER .Then instrument ask for buffer <6.5 or >7.5.
- 5.2.5 Before enter the value pH 4.0, remove the electrode from buffer pH 7.0 solutions and rinse with purified water and wipe with tissue paper.
- 5.2.6 Dip the electrode in buffer pH 4.0 solutions and press ENTER. Instrument ask for calibration1) Y 2) N. Select 1 and press ENTER.
- 5.2.7 Instrument ask for >7.5 pH buffer. Before select the value pH 9.2, remove the electrode from buffer pH 4.0 solutions and rinse with purified water and wipe with tissue paper then dip the electrode in buffer pH 9.2 solution. Press enter respectively. Instrument show the value of buffer pH 9.2.Press ENTER, instrument show "Calibration is over".
- 5.2.8 After calibration is over, wash the electrode with purified water, wipe with tissue paper and dip in fresh purified water.
- 5.2.9 Reading of Buffer pH 4.0 and 9.2 should be 4.0 (+ 0.05) and 9.2 (+ 0.05) respectively.After completion of calibration of Instrument Press Mode Key and Select pH mode by Enter
- 5.2.10 Press CAL Key and Note the Slope Value S1 and S2.The Slope value S1 for pH 4.00 and S2 for pH 9.2.

The Slope Value of Electrode not deviates from 80% to 120%.

- 5.2.11 Use buffer solution within 15 days from date of preparation Discard the buffer solution if any precipitate, turbidity or discoloration observed during storage.
- 5.2.12 Calibration Frequency Daily



	STANDARD OPERATING	G PROCEDURE					
Depart	ment: Quality Control	SOP No.:					
Title: C	Citle: Operation and Calibration of pH meterEffective Date:						
Superse	edes: Nil	Review Date:					
Issue D	Date: Page No.:						
5.2.13	Fill the calibration status on metallic calibration lab	el of the instrument, record the calibration					
	results in annexure-I						
5.2.14	If instrument is out of calibration, affix "UNDER MA	AINTENANCE" and call for service					
	engineer.						
5.3	Cleaning:						
5.3.1	Wash the pH electrode with purified water.						
5.4	Precautions:						
5.4.1	Handle electrode with care.						
5.4.2	Use buffer after attaining ambient temp.						
5.4.3	Change the Saturated KCl solution frequently.						
6.0	ABBREVIATION(S):						
	KCl - Potassium chloride						
	QCD - Quality Control Department						
	SOP - Standard Operating Procedure						
	NA - Not Applicable						
7.0	REFERENCE(S):						
	NA						
8.0	ANNEXURE(S):						
	Anneyure I: Calibration Record of pH meter						

Annexure- I: Calibration Record of pH meter.

9.0 **REVISION CARD:**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION		



PHARMA DEVILS QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Control	SOP No.:			
Title: Operation and Calibration of pH meter	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

ANNEXURE I

Calibration Record: pH meter					
Location		Model No.			
Make	Labindia	Identification No.			
Calibration Done		Calibration Due			
On		On			
Reference SOP No.:		Page No. : 4 of 1			

Month & Year: _____

At $25^{\circ}C \pm 2^{\circ}C$

Date	Standard pH 7.0 buffer		pH 4.0 pH 9.2 buffer buffer		Slope Value (80% to 120%)		Done by	Checked by	Remark
	Observed	Set to	Observed	Observed	S1	S2	-		