

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

One pharmaplan

pH Meter

Project No: 110729

Equipment ID: BF-PHM 01

Document No: DS/BF-PHM 01



1 Process requirements

1.1 To determine the pH of the raw materials, finished products, in process samples, various validation samples, etc. as per specified methods and/ or pharmacopeia monograph (EP/USP). It will be placed in the IPQC room(BF012) of the BCG Bulk first floor.

2 Technical Specification

2.1	Model	Basic cGLP waterproof model with combined glass electrode
2.2	Type	Digital
2.3	Expected operational hours per day	24 hrs with stand-by mode
2.5	Display	pH, temperature
2.6	Quantity	1 No
2.7 Utility		
2.7.1	Power required	Vendor to specify



3 Material of Construction

3.1	Glass Electrode	The glass electrode must be made from Borosilicate glass
3.2	Body of the pH meter	Powder coated or Vendor to specify

4 Specific requirement

- 4.1 The pH meter must be microprocessor based precision with automatic temperature compensation and digital interface.
- 4.2 The pH meter must have pH Electrode, stand with flexible arm, Electrode holder and universal power adaptor.
- 4.3 Instrument should be capable of accurate measurements of pH within the pH range of 2 to 14.
- 4.4 Accuracy of the pH measurement should be within ± 0.01 .
- 4.5 Resolution should be ± 0.01 pH or 0.1mV
- 4.6 Voltage range ± 1200 mV, Accuracy: $\pm 0.1\%$
- 4.7 Working Temperature will be ambient, Accuracy $\pm 0.1^{\circ}\text{C}$
- 4.8 Instrument should be capable of Multipoint calibration with max. 3 buffers as per USP ranges.
- 4.9 Ready made buffer solution of 4,7,10 to be provided - One set
- 4.10 Automatic temperature compensation for pH measurements.
- 4.11 LCD display to show the readings.
- 4.12 Display of pH value and temperature on the screen.
- 4.13 Spare pH electrode to be provided.
- 4.14 **Approved makes:**
a) Mettler-Toledo
b) Thermo

5 Other requirements

5.1 The instrument must be portable.

6 Regulatory guidelines / standards

NA

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7	Safety requirement					
7.1	Appropriate closure of all parts.					
7.2	Proper earthing.					
7.3	On power failure equipment should come in failsafe condition					
8	Documentation					
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file					
8.1	Operation and maintenance manuals.					
8.2	NPL traceable Calibration certificates and calibration procedures					
8.3	IOQ protocol					
8.4	Comprehensive one year warranty letter from date of completion.					
9	Timelines					
	NA					
	AFI Approved for Enquiry			AFO Approved for Ordering		
4	2014-02-05			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/1

18/3/19
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