






DATA SHEET		
HLL BIOTECH LIMITED, CHENNAI		
	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR	
	pH - Meter	
	Project No :	110831
	Equipment ID :	Refer LYT
	Document No :	DS/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).	
2	Technical Specifications	
2.1	Type	Digital, benchtop type
2.2	Model	Basic cGLP waterproof model with combined glass electrode
2.3	Display	pH, temperature
2.4	pH range	0.00 - 14.00
2.5	Resolution and Accuracy	0.01 ± 0.01 pH Voltage range, ± 1200 mV, Accuracy ± 0.01%
2.6	Temperature range	0 to 100 °C
2.7	Temperature Accuracy	± 0.1 - 0.5 °C
2.8	Calibration	minimum upto 3 points
2.9	Expected operational hour	24 hrs with stand-by mode
2.10	Power required	Vendor to specify
2.11	Quantity	8 nos
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 requirements	
4.1	Gell filled electrode should be provided	
4.2	The pH meter must be microprocessor based precision with automativc temperature compensation and digital interface.	
4.3	The pH meter must have, stand with flexible arm, Electrode holder and universal power adaptor.	
4.4	Working Temperature will be 0 °C - 50 °C	
4.5	Instrument should be capable of Multipoint calibration with max. 3 buffers as per USP ranges.	
4.6	Ready made buffer solution of 4,7,10 to be provided - One set	
4.7	Automatic temperature compensation for pH measurements.	
4.8	LCD display to show the pH and temperature readings.	
4.9	Expanded memory to store and recall minimum upto 50 data sets.	
4.10	Spare pH electrode to be provided.	
5	Other requirements	
5.1	NA	
6	Regulatory aspects	
6.1	NA	
7	Safety requirements	
7.1	Proper earthing.	
7.2	On power failure equipment should come in failsafe condition	
8	Documents	
	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	IOQ Protocol.	
8.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site	
8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	

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8.4	All equipment warranty should be valid for one year from the date of completion.					
8.5	Vendor should provide list of standard spare parts with ordering information.					
8.6	Vendor should provide list of change parts (if applicable) with ordering information					
9	<b>Timelines</b>					
	Not Applicable					
	AFI Approved for Enquiry			AFO Approved for Ordering		
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Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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HLL LIFECARE LIMITED, CHENNAI

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REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,  
COONOOR

pH - Meter

Project No : 110831

Equipment ID :

Document No : DS/PHM 01



TABLE NO: 1

Equipment Id	Block Name	Room Name	Room No	Quantity
B1-PHM-01	Diphtheria	IPQC	B1G057	1
B1-PHM-02	Diphtheria	Media and buffer room	B1G069	1
B1-PHM-03	Pertussis	IPQC	B1G018	1
B1-PHM-04	Meat Media Preparation	Meat store	B1G090	1
B2-PHM-01	Tetanus	IPQC	B2G026	1
F1-PHM-01	Formulation	Blending area	F1G057	1
M1-PHM-01	Sterility Media Preparation and Microbiology	Lab	M1G039	1
A1-PHM-01	Animal Breeding	Animal health monitor	A1G012	1

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