INSTALLATION QUALIFICATION PROTOCOL FOR pH METER

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

INSTALLATION QUALIFICATION PROTOCOL FOR pH METER

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned pH meter is installed as per design.
- To ensure that the pH meter installed confirms to purchase specifications and manufacturer literature, and to document the information that the pH meter meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**pH METER**
ID Number	**……**
Location	**Media Preparation Room**

3.0 Equipment / System Description:

For Compendial pH is defined as the value as the value given by a suitable by a suitable, properly standardized, potentiometeric instrument capable of reproducing pH values to 0.02 pH unit using an indicator electrode sensitive to hydrogen ion activity. The electrode and a suitable reference electrode. Measurements are made at 25 ± 2^0C.

The pH scale is define by the equation:

Ph = pH + (E - Es)

In which E & Es are the measured potentials where the galvanic cell contains the solution under test, represent buffer solution for standardization, represents by pHs respectively. The value of k is the change in potential per unit change in pH and is theoretically [0.05916 + 0.000198 (t - 25^0C)] volts at any temperature.

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4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

……
……
……
……

8.0 References:

Copy of Purchase order

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

Annexure - VII : Copy of Purchase order

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10.0 Abbreviations:

IQ : Installation Qualification

^0C : Degree Centigrade

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

INSTALLATION QUALIFICATION PROTOCOL FOR pH METER

Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	……..		
2.	Vendor's Name	Micro Device		
3.	Instrument Make	Metrohm		
4.	Instrument Model No.	827 pH Lab		
5.	Instrument Manual	Instrument Manual submitted by the vendor		

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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	pH Meter	827 pH Lab meter Serial No. 06333		
B.	**Location suitability**			
1.	Placement	Should be place In Media Preparation Room		
2.	Temperature	Ambient		
3.	Relative Humidity	Not More than 55 %		
4.	Bench Surface	Non Vibrating		
5.	Static Electricity	Negligible		
6.	Area	Free from strong magnetic field		
7.	Location	A location that minimizes the chance of water entering the underside		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
C.	**Utilities**			
1.	Electrical power supply	A Stable source of 240 VAC, 6VDC supply should be provided		
D.	**Safety**			
1.	Safety	pH meter should connect to a correctly installed line power outlet having protective conductor.		
		Should not make internal adjustment except as directed in the manual		
		Should not operate the pH meter with any covers or parts removed		
E.	**MOC Certificates**	Not Applicable		
F.	**Calibration Certificates**	Not Applicable		
G.	**Testing Certificates**			
1.	Instrument Inspection Certificate	Instrument Inspection Certificate provided		
H.	**Drawing Details**	**Drawing No.**		
1.	Not Applicable	Not Applicable		

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Annexure - III

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By:

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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

_____

_____

_____

_____

_____

Summary Report Prepared By:

Date & Sign