INSTALLATION QUALIFICATION

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PICO CONDUCTIVITY METER

(LABINDIA)

INSTALLATION QUALIFICATION FOR PICO CONDUCTIVITY METER

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1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No. ..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessary; an addendum will be prepared and approved.

Written By	Signature	Date
Officer/Executive- Quality Control		

Checked By	Signature	Date
Executive/Manager – Quality Control		
Executive/Manager – Quality Assurance		

Approved By	Signature	Date
Manager - Quality Assurance		
General Manager - Works		

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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is to provide an outline for the Installation Qualification of the instrument for static attributes to verify that:

- Each installed sub component complies with the instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.
- A *draft* Standard Operating Procedures (SOP) have been identified and listed.

2.2 Scope:

This protocol covers the installation qualification of the Pico Conductivity meter.

2.3 Responsibility:

The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this protocol:

- Engineering Department
- Quality Control Department
- Quality Assurance Department

Quality Control department shall be responsible for checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The summary report shall be approved by the Engineering, Quality control and Quality Assurance.

2.4 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

2.5 System Description:

Conductivity measurement is one of the most essential requirements in Quality control laboratories. Conductivity is the measurement of a materials ability to conduct electric current .The basic unit of conductance". "G" is the "Siemens" (formally called the Mho). Conductance is the reciprocal of resistance (measured in ohms). Measurement of conductivity of sample solution gives the degree of electrical conductance in a defined volume of the solution. Electrical Conductivity of the solution is proportional to the number of ions available in it. And hence conductivity measurement will give a direct reading of solution concentration.

The principle by which instruments measures conductivity is simple. Two conductivity plates are placed in a sample and a potential is applied across them (normally AC voltage) and then the current is measured. Conductivity can be determined from the voltage and current values. Because conductivity is affected by cell geometry, specific conductivity should be used. The specific conductivity can be calculated by multiplying the conductivity by the electrode cell constant. This constant is determined by the formula, length/area. The unit is µS/cm. The conductivity of the sample solution changes in temperature, the relation is given as below,

$Gt = Gtcal \{ 1+a(t-tcal)\}$

Where:-

Gt :- Conductivity at any temperature in ºC

Gtcal :- Conductivity at calibration temperature in ºC

a :- Temperature coefficient of solution.

tcal :- Calibration temperature

3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
CONDUCTIVITY	
Measuring Range	0.01 µS/cm to 1999.9mS/cm. (Depending on the Cell used 0.1/1.0 /10.0 K)
Resolution	0.001 (Displayed)
Accuracy	0.5 %
Temperature Coefficient	0.00 – 9.99 % /ºC (default + Last value,#1.92)
TDS (Optional)	
Measuring Range	0.1 PPM to 99.9 PPT (Depending on the Cell used 0.1/1.0 /10.0 K)
Resolution	0.01 (Displayed)
Accuracy	0.5 %
TDS Factor	0.100 – 0.900 (default = Last value ,# 0.5)
TEMPERATURE	
Temperature Range	0 to 99.9ºC
Resolution	0.1ºC
Relative Accuracy	+/_ 0.2 ºC
Sensor	RTD PT 100.
Temp. Compensation	Automatic/ Manual @ 20/25 ºC
DISPLAY	20 x 2 line Back lighted LCD display.
KEYBOARD	Alphanumeric splash waterproof polyester soft keys.

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ITEM	SPECIFICATIONS
REPORT FORMAT	• Report of selected Conductivity/TDS readings. • Conductivity Calibration Report
INPUT	2 No. Banana sockets for Conductivity Electrode 1 No. 5 pin Shell connector, ATC-PT 100
OUTPUT	Printer (Parallel)
ENVIROMENTAL OPERATING CONDITION	1. Operation : Indoor 2. Temperature : Ambient to 45ºC 3. Relative Humidity: 5 to 90 % non-condensing.
POWER REQUIREMENT	230 Vac / 50 Hz (+/- 10 %)

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4.0 Instrument Identification:

The subjected instrument is identified as

Serial No. : .....

In- house Instrument No. :

Name of the Supplier : LABINDIA INSTRUMENTS PVT. LTD.

Purchase Order No. :

5.0 Instrument Location:

Facility : Quality Control Department

Area : Quality Control Area

Room / Lab. Identification : Instrument Lab

6.0 Installation Qualification Procedure:

6.1 Inspection Checklist

Instructions:

6.1.1 Check the Instrument physically for any damage and record the observation in the Data Sheet of section 6.2.

6.1.2 Identify the utility supplies required for instrument operation. Verify that utilities are as per the specification mentioned in the Check Point and record the observation in the Data Sheet of section 6.2.

6.1.3 Identify the critical accessories supplied with the instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications.

6.1.4 Check the installation of instrument:

- To verify the proper assembly of the components as per the instrument manual. Record the installation location and verification of assembly in Test Data section 6.2.

6.1.5 Identify the SOPs and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.

6.1.6 Record the deficiency (if any) in section number 6.2 and report the details of action taken.

Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Incase of non-compliance, give the explanation / justification in the deficiency and corrective action report format under section 6.2.*
3. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*
5. *The calibration certificates of the instruments shall be traceable to National / International standards.*
6. *Define all technical terms and abbreviations in the appendix under section 10.0.*

6.2 Installation Qualification:

6.2.1 Physical verification of the instrument / Environment

Objective: To verify that any physical damage of the instrument and Environmental condition for the operation of the Instrument.

S. No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument and accessories for any damages.	There should not be any damages.		
2.	Installation table space leveling & Vibration	As per requirements. (leveled &free from vibration		
Environmental Conditions				
1.	Room Temperature	15° C to 32°C		
2.	Relative Humidity	20% to 80%		
3.	Sunlight	Away from the Sunlight		
4.	Air Shaft	No direct overhead fan or Air Conditioner		
5.	Vibrations	Free from Vibrations -		
6.	Gases	No corrosive Gases		
7.	Dust & Moisture	Free from excess dust and moisture		

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S. No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
8.	Flammable, toxic & Corrosive vapors	Instrument power cable & control cable connectivity with peripherals.		
Electrical Supply				
9.	Instrument electrical connectivity check	Instrument power cable & control cable connectivity with peripherals		
10.	Power Requirements	Servo Stabilized & Free from transients		
11.	Connection Sockets	5A-1/2 Nos.		
12.	Supply Voltage	230VAC,+-10%		
13.	Supply Frequency	50 Hz, +-10%		
14.	Earthing	Proper		
15.	Earth to Neutral Potential	Not more tan 3V		

	Name	Sign.	Date
Checked by (Engineering)			
Verified by (Quality Assurance)			

6.2.2 Major Component Verification

Objective: To verify that major components as identified below are complying as per the desired specifications.

S. No	Name	Part No.	Qty. Supplied	Observation	Acceptance Yes / No
1	Lab India PICO-Conductivity Meter With Power cord				
2	Conductivity Electrode –Cell Constant K =1 { Indian Make }				
3.	RTD for temperature sensing				
4.	Electrode Stand				
5.	Operator's Instruction Manual with Validation Certificate				
6.	**Accessories :**				
7.	Conductivity Electrode Cell Constant K=1.0 (Glass Body)				
8.	Electrode Holder				

Checked by (Engineering)

Name	Sign.	Date

Verified by (Quality Assurance)

Name	Sign.	Date

6.2.3 Verification of Utility Supply:

Objective: To verify that necessary utility supplies required for instrument operation are as per the desired specification and connected properly.

S. No.	Utility	Specifications	Observations	Connected and Identified (Yes / No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		

Note: *Power Supply to be checked with a Multimeter.*

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.4 Standard Operating Procedures (SOPs) Identification:

SOP's	Number	Title
Operation, Calibration and Cleaning		Conductivity meter – Model Pico

6.2.5 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____
_____

Conducted By : _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.

8.0 Remarks (if any):

_____

_____

_____

_____

_____

9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.	Yes/No	

9.1 Conclusion:

Pico Conductivity meter bearing Instrument No..... **is** / is **not** qualifying the Installation Qualification tests as per the Protocol ....., hence the instrument **can** / **cannot** be tested for its Operational Qualification as per Protocol No. .....

9.2 Post-Approval Signatures:

Name	Signature	Date
Manager - Engineering		
General Manager – Works		
Manager – Quality Assurance		

10.0 Appendix:

10.1 Abbreviations and Definitions

IQ	- Installation Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
cm	- Centimeter
N.A.	- Not Applicable
S. No.	- Serial Number
Sr.	- Senior
mV	- Milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
gm	- Gram
RH	- Relative Humidity
UPS	- Uninterrupted Power Supply
Kg	- Kilogram
Hr.	- Hour
Sec	- Seconds
S.S.	- Stainless Steel
Nos.	- Numbers
mAmp	- Milli Amperes
Amp	- Amperes
Eq.	- Equipment
USP	- United States Pharmacopoeia
Ph Eur	- European Pharmacopoeia
IP	- Indian Pharmacopoeia

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Acceptance criteria	:	The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.
Installation qualification	:	The documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications (e.g., construction, materials) and are correctly installed?
Validation	:	Establishing documented evidence that a system does what it purports to do.
Revalidation	:	Repetition of the validation process or a specific portion of it

10.2 List of Documents:

1. Instrument manual

2. Purchase Order Attached (Yes / No). If no, state Location.

   _____

   Purchase Order No. ..... Dated ..... is attached.

3. Calibration Certificates

4. Draft SOP – .....