Design Qualification

Automatic Leak Test Apparatus
Model: µLTCal$_{10}$

DESIGN QUALIFICATION

Protocol Number	**:**	ASIPL/DQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Automatic Leak Test Apparatus
Model	**:**	$\mu LTCal_{10}$
Instrument Sr. No.	**:**	
Protocol Approved By	**:**	Analab Scientific Instruments Pvt. Ltd.

PRE-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Prepared By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

DESIGN QUALIFICATION

"Design qualification (DQ) defines the functional and operational specifications of the instrument ". DQ should ensure that the instruments have all the necessary functions and performance criteria that will enable user to be successfully implemented for the intended application and to meet business requirements.

TECHNICAL SPECIFICATION

- Vacuum Controller : Microcontroller Based
- Material of Construction : Stainless Steel
- Maximum Vacuum Level **:** Better than 500 mm of Hg
- Vacuum Setting : Vacuum can stabilize for a set value from:
  Less than 400 mmHg: ± 10 mmHg within 30 seconds
  Above 400 mmHg : ± 5 mmHg within 30 seconds
- Vacuum Hold Timer **:** Variable from 1 sec. to 99 min
- Vacuum Release Timer **:** Variable from 1 sec. to 5 min
- Time **:** Real time clock
- Display **:**16 x 2 Line Alphanumeric Backlit LCD
- Keypad : Membrane waterproof polycarbonate soft touch keypad compliance to UL/ROHS
- Vacuum Gauge **:** Digital display by user friendly touch pad
- Auto Release of Vacuum : Yes – after completion of Vacuum Hold Time
- Power Supply **:** 230VAC ± 10%, 50Hz

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

DESIGN QUALIFICATION

The Design Qualification (DQ) for the Leak Test Apparatus has been reviewed and found acceptable for use.

INSTRUMENT	**:**	Automatic Leak Test Apparatus
MODEL	**:**	μLTCal$_{10}$
SERIAL NUMBER	**:**	
FINAL REPORT REVIEWED AND ACCEPTED BY		
(Name & Designation)	**:**	
DATE	**:**	

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

POST-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Executed By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

Installation Qualification
&
Operational Qualification

Leak Test Apparatus
Model: μLTCal$_{10}$

Version Number : _____

INSTALLATION & OPERATIONAL QUALIFICATION

Protocol Number	:	ASIPL/IQ-OQ/
Company Name	:	
Location	:	
Instrument	:	Automatic Leak Test Apparatus
Model	:	µLTCal$_{10}$
Instrument Sr. No.	:	
Protocol Approved By	:	Analab Scientific Instruments Pvt. Ltd.

PRE-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Prepared By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

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Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

1 INSTALLATION QUALIFICATION:-

Installation qualification establishes that the ordered instrument is received as designed and specified, that it is properly installed in the specified environment, and that this environment is suitable for the operation and use of the instrument.

1.1. Instrument Identification & Verification

Customer Purchase Order No. _____ Date_____

Main System Contents.

Sr. No.	Description	PO Qty.	Received Qty.	Remark	
				Ok	Not ok
01	Automatic Leak Test Apparatus Model : µLTCal10 Make : ANALAB				
02	Power Cord				
03	Silicon Tube				
04	Operational & Instruction Manual with SOP				
05	Calibration certificate				
06	Warranty Card				
	Optional (if ordered)				
07	DQ/IQ-OQ/PQ Documents				
08	Desiccator : Size - _____ mm				

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

_____	_____	_____
Analab Representative	Checked by End User	Approved by Head of Department

1.2. Pre-Installation Requisites & Verification

Check the installation place for fulfillment of manufacturer's recommendation. (Utilities such as Power requirement, necessary chemicals and environmental conditions such as humidity, temperature, light and dust etc. (Please refer Pre-Installation requisites attached with this document.)

Requirement	Condition	Observation		Remark	
		Ok	Not Ok	Pass	Fail
Instrument & Accessories appearance check	No Damage and Breakage to instrument & Accessories.				
Installation Table space Leveling & Vibration.	As per requirements.				
Power Requirements • Connections sockets • Supply Voltage • Earthing (Earth to Neutral Potential	• 5 Amps. 02 no. • 230 V AC ± 10% • Not more than 3 (Three) Volts.				
Environment conditions. 1) Sunlight 2) Air Draft 3) Room Temp. 4) Humidity 5) Dust 6) Flammable, Toxic & Corrosive Vapors	 Away from sunlight No direct fan or AC 15 ° ~ 50° C 20 ~ 80 % Free from dust Free from vapor.				

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

1.3. Installation Qualification Verifications

1.3.1. Instrument Identification & Verification

SR. NO.	DESCRIPTIONS	RESULT	
		Yes	No
A	Items received as per Purchase Order		

1.3.2. Pre Requisites Inspection

SR. No.	DESCRIPTIONS	RESULT	
		Yes	No
A	Instruments & Accessories Checked for Damages		
B	Table Space & Leveling		
C	Power Supply Availability		
D	Environmental Requirements		

1.3.3. Standard & Optional Accessories (as ordered)

SR No	DESCRIPTIONS	RESULT	
		Yes	No
1	Power Cord		
2	Silicon Tube		
3	Operational & Instruction Manual with SOP		
4	Calibration test certificate		
5	Warranty Card		
6	DQ/IQ-OQ/PQ Documentation (Optional)		
7	Desiccator : Size - _____ mm (Optional)		

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2 OPERATIONAL QUALIFICATION

Operational Qualification (OQ) is the process of demonstration that an instrument will function according to its operational specifications in the selected environment.

2.1. Customer Orientation & Training

Orientation for the end user/s will be performed as per the Instruction Manual.

Sr. No	Orientation Topic	Status	Verified	
			Yes	No
1	Instrument Setup/Connectivity with Accessories, Peripherals and Mains etc.	Explained / Shown		
2	Instrument Front Panel – Key Function	Explained / Shown		
3	Instrument Back Panel – Connection	Explained / Shown		
4	Instrument Mode & its function	Explained / Shown		
5	Instrument & Accessories Maintenance	Explained / Shown		

The Training on the above topics is given to following personnel

Personnel Trained	Designation	Location	Verified

The Instrument orientation and training were carried out in accordance with the Instruction Manual and found satisfactory.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2.2. Operational Checking & Verification

Ensure connection of Power cable and Desiccator with the instrument.
(Pl. refer instruction manual)

2.2.1. Power on Check

REQUIREMENT CONDITION & OBSERVATION	Result	
	Pass	Fail
➢ Display shows Manufacturer's Name , Model Number, Version Number, Serial Number and display factory set Company name		

2.2.2. Calibration with calibrated External Vacuum Gauge

Vacuum Applied mmHg	Vacuum Display (mmHg)		Deviation mmHg	Deviation Limit +/- 5 mmHg	Result	
	External Gauge	Instrument			Pass	Fail
000						
500						

2.2.3. Verification after Calibration (Deviation Limit - ± 10 mmHg)

Vacuum Applied mmHg	Vacuum Display (mmHg)		Deviation mmHg	Result	
	External Gauge	Instrument		Pass	Fail
000					
100					
200					
400					
500					

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2.2.4. Timer Test

Set Time on Instrument sec	Measured Time on Stopwatch in Sec	Acceptable Deviation Sec between	Result	
			Pass	Fail
60		50 - 70		
180		170 - 190		
300		290 - 310		

2.2.5. Error Message Check

Sr. No.	Observation at required conditions	Remark	
		Pass	Fail
01	Incomplete Calibration – when SPAN calibration not perform		
02	Check Vacuum Leakage in system/Desiccator		

2.3. Summary of Operational Checking & Verification

SR NO	DESCRIPTION	RESULT	
		Pass	Fail
01	Power ON Check		
02	Calibration with calibrated External Vacuum Gauge		
03	Verification after Calibration		
04	Timer Test		
04	Error Message Check		

All system components and functions are operating satisfactory.

The Operational check and the verification were carried out in accordance with the operating Manual and found satisfactory.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

INSTALLATION & OPERATIONAL QUALIFICATION

The Installation Qualification (IQ) & Operational Qualification (OQ) final reports for the Automatic Leak Test Apparatus have been reviewed and was found acceptable for user.

INSTRUMENT : Automatic Leak Test Apparatus
MODEL : µLTCal10
SR.NO. :
FINAL REPORT REVIEWED AND ACCEPTED BY (Name & Designation) :
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

POST-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Executed By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

Performance Qualification

Leak Test Apparatus
Model: μLTCal$_{10}$

Version Number : _____

PERFORMANCE QUALIFICATION DOCUMENT

Protocol Number	:	ASIPL/PQ/
Company Name	:	
Location	:	
Instrument	:	Automatic Leak Test Apparatus
Model Number	:	µLTCal10
Instrument Serial Number	:	
Protocol Prepared By	:	Analab Scientific Inst. Pvt. Ltd. Vadodara

PRE-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Prepared By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

PERFORMANCE QUALIFICATION

Performance Qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its use.

Note: PQ should always be performed under conditions that are like routine sample analyses.

1. Aim

To ensure that the $\mu LTCal_{10}$ is properly calibrated with traceable Vacuum Gauge. The test will check and confirm that the correct analysis should perform.

2. Scope

Performance Qualification must be performed in the case of new installation of an instrument or change in the location and / or as per FDA requirements.

3. Responsibility

The responsibility for the Performance Qualification lies with the system user.

4. Preparation for the Test

4.1. Apparatus Required:

1 Leak Test Apparatus : µLTCal10
2 Tissue Paper Roll.

4.2. Chemical Required:

1 0.5% Crystal violet Solution or any equivalent
2 Purified Water 1 ltr
3 Blister/Vial Samples

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

5. Performance check of Instrument:

5.1. Ensure that the leak test apparatus and Desiccator is clean and dry.
5.2. Open Desiccator lid and fill the Desiccator with pure water till strips get submerged in water.
5.3. Remove and clean O ring and groove of Desiccator with the help of soft dry cloth and remove any kind of dust particles and fix it again on the groove.
5.4. Set Vacuum and Time with respective keys on keypad for sample to be analyze.
5.5. Insert the strip or blister to be tested for leak test and place the resting plate into the desiccator and close the lid tightly and press **ENTER**, pump will start.
5.6. Actual Vacuum will start increasing.
5.7. Once set vacuum achieved, press timer on/Off key so on timer will starts
5.8. If vacuum is not increasing, then check for leakage.
5.9. Check and correct leakages with desiccator and restart pump.
5.10. Once actual vacuum reaches at set vacuum, pump will stop and allow vacuum to stabilize.
5.11. Actual Vacuum will hold up to set HOLD up to set time, and reverse time will start.
5.12. After Hold time completes, vacuum from desiccator will release automatically up to set release time
5.13. When complete vacuum release and display shows Zero, open the desiccator lid.
5.14. Remove strips/Blister and Wipe the strips/blister with tissue paper in order to remove water droplets.
5.15. Observe the strips/blisters for any water seepage inside. If seepage is observed, then it indicates failure of leak test.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

PERFORMANCE QUALIFICATION

The instrument has been checked and perform with samples. The test protocols have been filled in correctly and test results are documented. The system can be released for appropriate use.

INSTRUMENT : Automatic Leak Test Apparatus
MODEL : µLTCal10
SERIAL NO. :
FINAL REPORT REVIEWED AND ACCEPTED BY (Name & Designation) :
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Analab Representative | Checked by End User | Approved by Head of Department

POST-APPROVAL

Name and Designation of Authorized Person	Signature	Date
Executed By: ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD. - VADODARA		
Reviewed By:		
Approved By:		

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department