INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

(JICON – MAKE)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

TABLE OF CONTENTS

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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
Manager - Engineering		

Checked By	Signature	Date
Manager – Production		
Manager – Quality Assurance		

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

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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 Leak Test Apparatus (JICON – Make).

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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
- Production Department
- Quality Assurance Department

Engineering 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, Production 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.

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

2.5 System Description:

Leak Test Apparatus is an ideal instrument to check blister packs, strips for leak test. The old method of separate dessicator and huge vacuum pump is replaced with this new Leak Test Apparatus in GMP Stainless Steel body with phenomenal compactness.

The instrument is equipped with long lasting vacuum pump, which gives higher level of vacuum in shortest possible time. Die pressed polycarbonate vacuum dessicator sustains vacuum for a long time.

A vacuum gauge is provided to indicate vacuum level, which is connected to isolation valve to disconnect the vacuum source. Thus avoiding the need of continuous running of vacuum pump. A 0 to 5 minute timer helps operator to do the other work. Its amazing compactness saves lot of valuable place in process laboratories.

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Dessicator Diameter	300 mm
Dessicator	Polycarbonate
Vacuum Level	550 mm of Hg
Rating	230 VAC ± 10 V, 5A, 50 Hz, Single phase
Timer	5 Minute (Mechanical)
Body	SS – 304

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

4.0 Instrument Identification:

The subjected instrument is identified as **Leak Test Apparatus**

(JICON – Make)

Serial No. : _____

In-house Instrument No. : _____

Name of the Supplier : _____

Purchase Order No. : _____

5.0 Instrument Location:

Facility	:	Manufacturing
Area	:	Process Area
Room / Lab. Identification	:	In-process Quality Control (IPQC)

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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 SOP's 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.*

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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.*

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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 for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	15° C to 30°C		
2.	Relative Humidity	45% to 70%		
3.	Away from the Sunlight	-		
4.	Free from Vibrations	-		
5.	No corrosive Gases	-		
6.	Free from excess dust and moisture	-		
7.	Stability of input power (± 10% of 230 v AC 50 Hz)	-		

Checked by (Engineering)

Name	Sign.	Date

Verified by (Quality Assurance)

Name	Sign.	Date

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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	Qty. Supplied	Observation	Acceptance Yes / No
1	Main Power Cord	1		
2	Bellow pump for removing water	1		
3.	Dust cover	1		
4.	Wiping cloth	1		
5.	Dessicator (in situ)	1		
6.	Instruction Manual	1		

Checked by (Engineering)

Name	Sign.	Date

Verified by (Quality Assurance)

Name	Sign.	Date

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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**

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

6.2.4 Standard Operating Procedure (SOP) Identification:

SOP's	Number	Title
Operation and Cleaning		Leak Test Apparatus (JICON – Make)

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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: _____

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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) :

_____

_____

_____

_____

_____

_____

_____

_____

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

9.0 Summary:

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

9.1 Conclusion:

Leak Test Apparatus (JICON – Make) 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		

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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

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QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

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

INSTALLATION QUALIFICATION FOR LEAK TEST APPARATUS

10.2 List of Documents:

1. Instrument manual
2. Purchase Order No. _____ Dated: _____. Attached (Yes / No). If no, state Location _____
3. Calibration Certificates
4. Draft SOP – .....