OPERATIONAL QUALIFICATION FOR LEAK TEST APPARATUS

(JICON – MAKE)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

OPERATIONAL QUALIFICATION FOR LEAK TEST APPARATUS

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1.0 Pre-Approval:

Signing of this Approval page of Operational Qualification Protocol No. ....., indicates agreement with the Operational Qualification approach described in this document. Should Modifications to the Operational 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		

OPERATIONAL QUALIFICATION FOR LEAK TEST APPARATUS

2.0 Overview

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Operation Qualification*, critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2 Scope:

This protocol covers the Operational qualification of the Leak Test Apparatus (JICON – Make).

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2.3 Responsibility:

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

- Production Department
- Quality Assurance Department
- Engineering Department

The Production and -Engineering shall be responsible for checking the operations and recording data as per the procedures outlined in this protocol.

Engineering shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Production and Quality Assurance.

The post approval of the qualification shall be done by the Quality Assurance and plant Head.

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2.4 Requalification:

Operational Qualification to be repeated incase of

- Replacement of any major component -
- Major modification in the existing instrument -
- During monitoring if instrument. is found to be malfunctioning -
- Shifting of the instrument from one location to another -

2.5 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. : _____

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3.0 Operational Qualification Procedure:

1) A draft SOP shall be prepared on the basis of manufacturer guide / instrument manual for operation before the Qualification testing.
2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the Manufacturer / supplier on the operational features of the instrument. This training shall be recorded in Section 3.1.
3) The trained personnel shall carry out the Operational Qualification along with the Service Engineer, following the Procedures mentioned under Section 3.2.1 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1. Checkpoints designed for the purpose of OQ are also aimed at verification of these draft SOPs.
4) Operate the instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.
5) Report the deficiency from the specified function, if any in the section 3.4

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3.1 Training **Date:**

Title: Leak Test Apparatus (JICON – Make)

Name of the Trainer(s): _____

S.No.	Name of the Trainee	Employee Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Signature of Trainer(s): _____

Date : _____

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3.2. Key Functionality & Safety Features:

A. Purpose:

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Leak Test Apparatus function as specified by the manufacturer.

B. Testing:

1. Turn on the power from the electrical panel.
2. Verify functionality of each component against its Specified functions.

5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

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3.2.1 TEST DATA SHEET (Confirmation of Services Connection):

S.No.	Test Particulars	Specified Function	Observations	Checked By
1.	Switch 'ON' the main supply	The instrument should switch 'ON' and the vacuum pump will be started		
2.	After switching on the instrument vacuum pump will start	Gradually the vacuum will start developing in the dessicator, which is indicated on the vacuum gauge.		
3.	After the reading of 15 mm of Hg is reached on the gauge, close the isolation valve	Isolation valve should get closed and vacuum should stop on 15 mm on Hg for required period of time.		
4.	Allow the blister strips in this condiction for 2 min by setting timer.	When the set time on the timer has elapsed, vacuum pump will be automatically switched 'OFF'		
5.	Remove the vent plug to release the vacuum	Vacuum should get released.		

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3 SOP Verification:

Draft SOP No. : .....

Title : Leak Test Apparatus (JICON – Make)

Operate the instrument. as per the draft SOP and record the details given below:

Operated By: ……

Checked By: ……...

The operating personnel understand and follow the SOP description (Yes/No) : YES

Changes required in draft SOP (If any) : _____

_____NO_____

_____

SOP to be revised (Yes/No) : NO

If yes, Review No. _____

Remarks : SOP Confirmed / Not Confirmed

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write N. A

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: _____

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4.0 Acceptance Criteria:

Operational Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 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.

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5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.		

5.1 Conclusion:

Leak Test Apparatus (JICON – Make) **is / is not** qualifying the Operational Qualification tests as per Protocol No..... The Instrument **can / cannot** tested for its Performance Qualification as per Protocol No.....

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5.2 Post-Approval:

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

6.0 Appendix:

6.1 Abbreviations and Definitions

OQ	-	Operation 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
g	-	Gram
RH	-	Relative Humidity
USP	-	United States Pharmacopoeia
SOP	-	Standard Operating Procedure

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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.
Operational qualification	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality operate as intended throughout all anticipated ranges.
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