OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
LEAK TEST APPARATUS

EQUIPMENT ID. No.	
LOCATION	**Ointment Section, Packing hall**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Leak Test Apparatus and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Leak Test Apparatus (Make: ……)** installed in the **Ointment Section Packing Hall**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Leak Test Apparatus.
- Successful completion of this Protocol will verify that Leak Test Apparatus meet all acceptance criteria and ready for Performance Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Authorized and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments.

5.0 EQUIPMENT DETAILS:

Equipment Name	Leak Test Apparatus
Equipment	
Manufacturer's Name	
Model	
Sr. No.	
Supplier's Name	
Location of Installation	Ointment Section, Packing Hall

6.0 EQUIPEMENT DESCRIPTION:

Leak test apparatus is designed to check leakage sealing bottles/ tubes etc. It is fitted with vacuum pump, digital microprocessor based timer (15- 999 sec) and vacuum gauge range 150-600 mmHg.

- Test the integrity of Sealed Bottles/tubes.
- Operation based on vacuum

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and Deviation should be approved.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective person.

7.2 Training Record of Validation Team:

All the persons involved in the execution of Re-qualification Protocol must be trained in all aspects of the Re-qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

Training shall be imparted to persons involved in temperature mapping activity and shall be recorded as follows;

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK TEST APPARATUS	PROTOCOL No.:

Training Title:

Venue:

Trainer Name: **Date of Training:**

S.No	Name of Employee	Employee Code	Department	Designation	Sign/Date
Training Given By: **Sign & Date**					

**Note: Training evaluation shall be done on the basis of oral assessment.*

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	DQ Protocol cum Report		
2.	IQ Protocol cum Report		
3.	SOP for Handling of Leak Tester Apparatus		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date:……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilized and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 Operational and Functional Checks:

Operate the Vial Washing Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Set the vacuum at minimum range	Vacuum Should able to create desired in jar through any leakage at minimum range 150 mm Hg		
Set the Vacuum at optimum range	Vacuum Should able to create desired in jar through any leakage at Optimum range 350 mm Hg		
Set the vacuum at maximum range	Vacuum Should able to create desired in jar through any leakage at minimum range 600 mm Hg		
Digital timer	Time counting in digital timer should be as per set parameter i.e. Hold time-180 Sec. Retention Time–15 Sec. Delay Time–15 Sec.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.5 Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Press Start Push Button	Equipment should Stop		
	Equipment should Start		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.6 Challenge Test: 6 X 3 Nos Leakage bottles/tubes Consider as Challenge bottles/tubes**.** Leak Test Should be Performed pre Leakage bottles/tubes as Per Desired Vacuum Pressure / as Per SOP. Challenge Test shall be performed three times.

Time		Vacuum Pressure	Bottle / Tube no.					
From	To	Hold Time	1	2	3	4	5	6
Acceptance criteria: Wrapped bottles /tube tissue paper should be wet**.**								

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Standard operating procedure for Leak test apparatus.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- SOP
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
LTA	:	Leak Test Apparatus
Ltd.	:	Limited
MOC	:	Material of Construction
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
Pvt.	:	Private
SS	:	Stainless Steel
WHO	:	World Health Organization

17.0 POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			