INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
LEAK TEST APPARATUS

EQUIPMENT ID. No.	
LOCATION	**Packing hall**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

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PHARMA DEVILS	INSTALLATION 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 carry out the Installation Qualification of Leak Test Apparatus to be used for inspection of bottles contains any foreign particles, broken Bottles/Ointment or not properly sealed bottles.
- To confirm that the equipment and its components are as per the Specifications and installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment safely, effectively and consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Leak Test Apparatus (Make: …….)** to be installed in the Ointment section packing hall.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.

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, approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Installation Qualification study as per Protocol.
Engineering	• Review of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Leak Test Apparatus Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM 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 150-600 mm Hg.

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

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Executed and approved design qualification document.
- Piping and Instrumentation Diagram (P& ID).
- Electrical Circuits Diagram.
- Technical Specification of Equipment.
- Calibration Certificate of Components.
- Certificate of Material of Construction of Components.

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 approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation (Satisfactory / Non Satisfactory)	Observed by (Engineering) Sign/Date
1.	Check the proper mechanical installation of Leak Test Apparatus.		
2.	Check the proper electrical installation of Leak Test Apparatus.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation (Complies / Non Complies)	Observed by (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled.		
Edges of Parts	Metal edges should be properly Rounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Ointment section , packing hall		
Illumination	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.3 Installation Checks:

S. No.	Critical Variables	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
1.	**Equipment**	Leak Test Apparatus		
2.	**Make**	…….		
3.	**Sr. No.**	…….		
4.	**Model**	1961		
5.	**Dimension**	366 X 310 X 230 mm (L X B X H)		
6.	**Desiccator ‘ size**	12 Inch		
7.	**Display**	12 X 4 Line		
8.	**Display**	16 Soft Touch Keys		
9.	**Weight**	12Kg		
10.	**Power supply**	AC mains, Voltage : 230 volts Watt : 500 watts		
11.	**Vacuum pump**	For vacuum		
12.	**Vacuum gauge**	For measuring pressure level 400 mm Hg Least count : ±10 In/ Hg Mounting type : panel mounting 1/8” B.S.P Threading		
13.	**Digital timer**	15- 999 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 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation (Complies/Non Complies)	Observed By (Engineering) Sign/Date
1.	**Body**	Polycarbonate		

8.5 SAFETY:

Checks	Acceptance Criteria	Observation (Complies/Non Complies)	Observed By (Engineering) Sign/Date
Well embedded equipment	For Leak Test Analysis		
Electrical wiring and Earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.		
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and operator safety.		
Noise Level	Below 80 db		

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

- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PRE-DEFINED 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 Practice
DQ	:	Design Qualification
HP	:	Horse Power
LTA	:	Leak Test Apparatus’
Ltd	:	Limited
mm	:	Millimetre
MOC	:	Material of construction
NLT	:	Not Less Then
No.	:	Number
Pvt	:	Private
SS	:	Stainless Steel

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:

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HEAD (QUALITY ASSURANCE)			