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:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

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 vial contains any foreign particles, broken vial or not properly sealed vial.
- 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** to be installed in the **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	• Initiation, 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 Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of 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). • Post Approval of Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Leak Test Apparatus
Equipment	……
Manufacturer's Name	Progressive Instrument
Model	cGMP Model
Supplier's Name	Progressive Instrument
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Leak test apparatus is designed to check leakage in the blister packs, strip, vacuum sealing bags etc. is used to test for the integrity of packed strips, blisters and small sachets containing tablets, granulates liquids and so on. The instrument is used to test the quality of the packaging process and to check that the seals enclosing the product are perfectly intact. It is fitted with vacuum pump, digital microprocessor based timer (upto 999 sec) and vacuum gauge 20" of Hg.

- Test the integrity of strips, blisters and bottles
- 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 and approved by respective authorities.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation	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:

S.No.	Installation Checks	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
1.	**Leveling**	Should be properly balanced and leveled.		
2.	**Edges of Parts**	Metal edges should be properly Rounded off without any sharp edges.		
3.	**Welding of Joints**	Welding of joints should be without any welding burrs.		
4.	**Place of Installation**	Packing Hall		
5.	**Room Condition**	General working condition. As per GMP and production requirement.		
6.	**Illumination**	NLT 300 Lux.		
7.	**Working space around the equipment**	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

Verified By
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Sign/Date: ……

Inference:

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Reviewed By
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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.	**Model**	LTA-300		
3.	**Dimension**	41 cm x 61 cm x 22 cm		
4.	**Conveyer Height**	As per Line Height		
5.	**Weight**	15 Kg		
6.	**Power supply**	AC mains, Voltage : 230 volts Watt : 500 watts		
7.	**Vacuum pump**	For vacuum		
8.	**Vacuum gauge**	For measuring pressure level 20” Hg Accuracy : ± 0.5% of full scale Least count : 0.2 In/ Hg Mounting type : panel mounting 1/8” B.S.P Threading		
9.	**Digital timer**	Up to 999 sec		

Checked By
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Inference:

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Sign/Date: ……

8.4 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	**Body**	SS -304 Q Fabrication		

8.5 SAFETY:

Checks	Acceptance Criteria	Observation	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.
- Calibration certificates.
- 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:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
MOC	:	Material of construction
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimetre
HP	:	Horse Power
AMP	:	Ampere

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			