INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
VACUUM LEAK TESTER

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Vacuum Leak Tester.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Vacuum Leak Tester to be installed Packing Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vacuum Leak Tester.

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, 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. • Post Approval of Installation Qualification Protocol Cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Vacuum Leak Tester Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol Cum Report after Execution.

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Vacuum Leak Tester
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

Vacuum Leak Tester is a equipment to find out leak in the flexible plastic blown Vials /Ampoules after filling & sealing, which is very essential in Pharma products to check individually on mechanical system like LVP/SVP containers, is a time consuming process, hence as a lot it can be checked under Vacuum in vertical position & then upside down to ensure the checking of complete Vials / Ampoules Surface. This process can be carried out in Vacuum Leak Tester with an adjustable cycle.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Instrumentation diagram
- Technical specification of equipment
- 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.

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Packing area		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Check that all components are installed in the location specified in Equipment Location Diagram**.**	All components are installed in the location specified in Equipment Location Diagram**.**		
Check any physical damage to the equipment.	No any physical damage to the equipment.		
Check the proper electrical installation of Vacuum Leak Tester.	The proper electrical installation of Vacuum Leak Tester.		

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 VACUUM LEAK TESTER	PROTOCOL No.:

8.1 Technical Specifications/Key Design Features:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Manufacturer	……		
Machine sr. No.:	G15016		
Overall Dimension (L x W x H)	2000 x 1100 x 1500 mm (Approx)		
Case Dimension (L x W x H)	610 x 610x 610 mm		
Net Weight	650 Kg (Approx)		
Vial/ Ampoules Cassette Size	For 5 ml & 10 ml LVS/ SVP/WFI oval/Round shape Vial/ Ampoules of Height up to 100 mm. Height. 1) Ø 15 x 82 mm Height. Vials 2) Ø 15 x 100 mm Height. Vials		
Capacity of Chamber	Minimum 13500 nos. Vials		
Chamber Size (W x H x D)	700 x 700 x 795 mm deep Chamber of 8 mm Thick, SS304		
Chamber Door	One Side Fix & other side 8 thickSS304operable door with suitable hinge, Gasket & Lock		
No of Tray	6 Tray/ Chamber, of 16 SWG Thick SS 304 with Perforation at bottom & Perforated Top sheet.		
Tray Size	665 x 100 mm Height x 795 mm Length for Ø 15 x 82 & 100 mm Height Vials		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM LEAK TESTER	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Driving Unit	Suitable Driving Arrangement with AC. Motor & Gear box Housed in SS Cage duly Matt Finished. Without Starter/ AC Drive.		
Main Drive Motor	Make : Crompton Model : YGPH Phase : 3Phase 415 V± V AC Ratio : 30 :1 Sr. No : ISI2468		
Main Drive Gear Box	Make : ‘ Yash ‘ of Suitable Size Model : YGPH Size : 3.00 Ratio : 30 :1 Sr. No : 20018		
Worm & Worm Wheel for Tilting	Ratio : 45 : 1		
Pulley on Motor	V- Groove Pulley, Sec-B, 3’’ Dia.		
Pulley on Gear Box	V- Groove Pulley, Sec-B, 3’’ Dia.		
V-Belt	B-30		
Chain Wheel	On Gear box & main Shaft T-16 x 5/8’’ P (2 Nos)		
Control Panel	Make : Maharishi		
PLC	Make : Schneider		
Touch Screen HMI	Make : Schneider		
Vacuum Pump	Make: ACMEVAC pump & Eng. Pvt. Ltd Model : ISP 1500		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Metal Proxy sensor	Make : Autonics Model : PR12-4DP-CN Size : 12 mm Qty : 2 Nos		
Vacuum Sensor	Make : Winter Type : 1/3 DAR,420 MA Sr.No. : LE10030R11		

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

Inference:

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

8.2 Material of Construction:

S.No.	PARTS NAME	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Main Body	SS 304		
2.	Vacuum Chamber	SS 304		
3.	Chamber Door	SS304		
4.	Tray	Aluminum		
5.	Drive Unit	SS		
6.	Drain Valve	SS		

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Sign/Date: ……

8.3 Safety:

S.No.	PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Building Joint	Building Joint Free From Building Burr		
2.	Sharp Edge.	No Sharp Edge Present		
3	Electrical wiring and earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided		
4.	Oil Level	Oil Level Should be up to Mark		
5.	Lubrication	Gear box Should be Lubricated by Lubricant		
6.	Chilled water Supply	Chilled Water Supply Properly Connected		
7.	Door With Gasket	Rubber Gasket Provided at Door for Properly air Tight Closing		

Checked By
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Sign/Date: ……

Verified By
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Sign/Date: ……

Inference:

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Reviewed By
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Sign/Date: ……

8.4 Utility Connection:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	• Voltage: 220-230 V AC • Phases: 1 Phase • Frequency: 50-60 Hz • Power consumption :310 Watts		
Earthing	Earthing Properly Connected.		
Chilled Water Supply	Chilled Water inlet & Outlet Pipe Properly Connected.		

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:

- Design Qualification Party Document
- Installation Qualification Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC
- If any other Document Required.
- Calibration certificates

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:

AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practices
VLT	:	Vacuum Leak Tester
FFS	:	Form Fil Seal
HP	:	Horse Power
Hz	:	Horse Power
mm	:	Millimeter
MOC	:	Material of Construction
Nos.	:	Number
Pvt.	:	Private
SS	:	Stainless Steel
V	:	voltage

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION			