OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
VACUUM LEAK TESTER

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL 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 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 Vacuum Leak Tester 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 **Vacuum Leak Tester (Make – …….)** installed Packing Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Vacuum Leak Tester for OQ. Successful completion of this Protocol will verify that Vacuum Leak Tester 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, Authorization and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Dynamic Pass Box Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational Qualification Protocol cum Report after Execution.

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:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- Draft SOP Operation & Cleaning of Vacuum Leak Tester

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 OQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

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)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Draft SOP for Operation & Cleaning of Vacuum Leak			

8.2 Test Equipment Calibration:

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT ID	CALIBRATION ON	DUE ON	OBSERVED BY SIGN / DATE

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 Vacuum Leak Tester as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Press ON on HMI	Motor should be start		
Press OFF on HMI	Motor should be stop		
	Blower should be Stopped.		
Press Switch OFF Position	Light should get OFF.		

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 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: ……

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9.0 REFERENCES:

- Design Qualification Party Document
- Installation Qualification Party Document
- Operation Qualification Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.
- Calibration Certificate of Test Instrument.

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 Practice
DQ	:	Design qualification
DYP	:	Dynamic Pass Box
IQ	:	Installation Qualification
Ltd.	:	Limited
mm	:	Millimeter
Nos.	:	Number
OQ	:	Operational Qualification
PO	:	Purchase Order
Pvt.	:	Private
QA	:	Quality Assurance

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			