PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM LEAK TESTER

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM LEAK TESTER	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM LEAK TESTER	PROTOCOL No.:

1.0 PROTOCOL – 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 that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The score of this protocol is limited for performance qualification of Vacuum Leak Tester installed in **FFS Packing Area**.
- This protocol provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review of Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Pre Approval of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review & Pre Approval of Performance Qualification Protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & Preventive maintenance as per schedule.
External Qualification Agency (if Applicable)	• Performance of qualification activity as per protocol

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 REASON FOR QUALIFICATION:

- New equipment installed in Packing Area.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

- Vacuum Leak Tester installed in Packing Area.

9.0 FREQUENCY OF QUALIFICATION:

- Initially
- Major Breakdown
- Yearly ±1 Month

10.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

10.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) SIGN/DATE	VERIFIED BY(QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report				
2.	Executed and approved Installation Qualification cum report				
3.	Executed and approved Operational Qualification cum report				

Inference:

……

……

……

Reviewed By:
(Manager QA)
(Sign & Date) ……....

11.0 TESTS AND CHECKS:

The following performance test have been carried out in order to demonstrate the Performance in Conformance

11.1 Objective:

- To verify the leakage presence in the Respules.

11.2 Procedure:

11.3 Clean the vacuum chamber Internally and Externally before start and after completion of a batch, make ensure for absence of respules of Previous Load.

11.4 Check the oil level in the Vacuum Pump, It should be optimum level.

11.5 Load the chamber with filled espouses in perforated Trays (06 Trays at a time, each tray with 2750 ,total 16500 in a LOT). The respules should be in upright position in the Tray.

11.6 Close the chamber door & tighten the clamps. Close the outlet valve below the Chamber.

11.7 Start the Vacuum Pump by pressing the start switch on at the panel board/HMI.

11.8 Check the printer, it should be on condition, Vacuum between 500 mm of Hg To 550 mm of Hg Will reach & hold for minimum 15 minutes in straight position. Thereafter Vacuum is released chamber is moved in upright position & again Vacuum hold for minimum 15 minutes for above mentioned range.

11.9 The Chamber will come back to its original position after release of Vacuum.

11.10 After complete release of Vacuum, open the Drain Valve at the bottom of the Chamber, to drain of any contents of the Leak respules.

11.11 Loose the clamp of Chamber door & open it.

11.12 Take out all the Trays and Inspect for leakages/Empty respules, clean the respules externally with a mopping pad if any dirty.

11.13 Collect the rejected respules in a container labeled as “Non Recoverable” and send the Rejection to scrap yard for destruction.

11.14 Performance of Vacuum Leak Tester Evaluate by Using Three Batches.

11.15 CHALLENGE TEST

11.15.1 Take 5 respules (one cassette) and make one micro hole in each with 22 gauge needle and mark them with Permanent Marker.

11.15.2 Place these micro holed respules in the third no. SS tray, With Batch located in the middle of the Chamber.

11.15.3 Record in Performance Qualification Report.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

S.No.	NAME OF TEST OR CHECK	EXECUTION (YES/NO.)	REMARK	VERIFIED BY (SIGN & DATE)
1.	Evaluation of Performance by Using First Batch			
2.	Evaluation of Performance by Using Second Batch			
3.	Evaluation of Performance by Using Third Batch			

Inference:

……

……

……

Reviewed By:
(Manager QA)
(Sign & Date) ……....

13.0 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."
- SOP for Vacuum Leak Tester

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Document

15.0 NON COMPLIANCE:

- In case of any Non-Compliance observed during performance test, inform to head QA for required action.
- All the required action should be addressed in the report and justified.

16.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

18.0 ABBREVIATIONS:

%	:	Percent
FFS	:	Form Fill Seal
GMP	:	Good Manufacturing practice
ID.	:	Identification
ISO	:	International standard of organization
LTD	:	Limited
min	:	Minute
mm	:	Millimeter
SOP	:	Standard operating procedure
VLT	:	Vacuum Leak Tester
WHO	:	World Health Organization