PERFORMANCE QUALIFICATION REPORT FOR VACUUM LEAK TESTER

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

REPORT CONTENTS

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

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

1.0 REPORT 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 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 report is limited for qualification of Vacuum Leak Tester installed in **Filling to FFS Packing Area**.
- This report 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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation , Review , Authorization and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification report after Execution.
Engineering	• Reviewing of qualification Report for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification report after Execution.
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	

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:

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.

7.1 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 (ENGINEERING) 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				
4.	Approved PQ Protocol				

Inference:

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

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

8.0 TESTS & CHECKS:

8.1 EVALUATION OF PERFORMANCE By USING FIRST BATCH:

8.1.1 Cycle-01

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.1.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.1.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.2 EVALUATION OF PERFORMANCE BB USING SECOND BATCH:

8.2.1 Cycle-01

Date of test		Equipment ID No.	
Product Name		Batch No.	
Vacuum observed		Vacuum Hold Time	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.2.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.2.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.3 EVALUATION OF PERFORMANCE BY USING THIRD BATCH:

8.3.1 Cycle-01

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.3.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

8.3.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Vacuum observed		**Vacuum Hold Time**	

Respule No.	Observation	Respule No.	Observation
1		11	
2		12	
3		13	
4		14	
5		15	
6		16	
7		17	
8		18	
9		19	
10		20	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Respoules to be found less than initially Filled vial or vial should be found empty

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

9.0 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:

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Reviewed By
(Manager QA)
Sign/Date:……

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Document

11.0 NON COMPLIANCE:

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12.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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13.0 CHANGE CONTROL, IF ANY:

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14.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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15.0 CONCLUSION:

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16.0 RECOMMENDATION:

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17.0 ABBREVIATIONS:

VLT	:	Vacuum Leak tester
FFS	:	Form Fill Seal
m^3	:	meter cube
min	:	Minute
mm	:	Millimeter
NA	:	Not Applicable
No.	:	Number
PVT	:	Private
QA	:	Quality Assurance
SOP	:	Standard operating procedure

18.0 REPORT 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			