PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

REPORT CONTENTS

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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 Leak Check Machine installed in **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.

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

5.0 EQUIPMENT DETAILS:

Equipment Name	Leak Check Machine
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

Leak Check Machine is designed to check the leakage from specified size and diameter of IV bottles by fix speed and conveying of bottles for next operation.

Complete machine can be divided in following sub sections.

- Structure of machine
- Mechanism of drive unit with DOL starter.
- Slat conveyor.
- Nylon wheel & star plate, Pressure rod.

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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:

……

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.1.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm^2		

Bottle No.	Observation	Bottle No.	Observation
1		**8**	
2		**9**	
3		**10**	
4		**11**	
5		**12**	
6		**13**	
7		**14**	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.1.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		**8**	
2		**9**	
3		**10**	
4		**11**	
5		**12**	
6		**13**	
7		**14**	
ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.2 EVALUATION OF PERFORMANCE BB USING SECOND BATCH:

8.2.1 Cycle-01

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		**8**	
2		**9**	
3		**10**	
4		**11**	
5		**12**	
6		**13**	
7		**14**	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.2.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.2.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.3 EVALUATION OF PERFORMANCE BY USING THIRD BATCH:

8.3.1 Cycle-01

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.3.2 Cycle-02

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

8.3.3 Cycle-03

Date of test		**Equipment ID No.**	
Product Name		**Batch No.**	
Applied Pressure	0.75 to 1.0 kg/cm2		

Bottle No.	Observation	Bottle No.	Observation
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	

ACCEPTANCE CRITERIA: The Fill Volume of pin hole marked Bottles 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:

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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:

……

……

……

……

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

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Document

11.0 NON COMPLIANCE:

.....

.....

.....

.....

12.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

.....

.....

.....

.....

.....

.....

.....

13.0 CHANGE CONTROL, IF ANY:

.....

.....

.....

.....

.....

.....

.....

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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

.....

.....

.....

.....

.....

.....

15.0 CONCLUSION:

.....

.....

.....

.....

.....

.....

.....

.....

.....

16.0 RECOMMENDATION:

.....

.....

.....

.....

.....

.....

.....

.....

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

17.0 ABBREVIATIONS:

VLT	:	Leak Check Machine
m^3	:	meter cube
min	:	Minute
mm	:	Millimeter
NA	:	Not Applicable
No.	:	Number
PVT	:	Private
QA	:	Quality Assurance
SOP	:	Standard operating procedure

PERFORMANCE QUALIFICATION REPORT FOR LEAK CHECK MACHINE

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			