PERFORMANCE QUALIFICATION PROTOCOL FOR LEAK CHECK MACHINE

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

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PROTOCOL CONTENTS

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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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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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 Leak Check Machine.
- 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

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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.

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7.0 REASON FOR QUALIFICATION:

- New equipment installed.
- After completion of the Operation Qualification of the Equipment's, 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:

- Leak Check Machine installed.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every 5 Year ±1 month.
- After any major breakdown or after major modification.
- After Change of Location.

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 TRAINING OF EXECUTION TEAM:

Provide the training to a team for the execution of protocol before execution of the same. Record of training shall be recorded in the Performance qualification Report.

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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 Bottles.

11.2 Procedure:

11.3 Clean the machine before start the trial.

11.4 Ensure the tightness of all the bolts, nuts, to avoid accident, please before starting the machine every time ensure that nothing is falling off between the tables.

11.5 Set the Machine according to the size of Bottle.

11.6 Set the desired pressure as per SOP to check the leakage of Bottles.

11.7 Run the machine according to the SOP.

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

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

11.10 Performance of Leak Check Machine Evaluate by Using Three Trial of each Batch.

11.11 CHALLENGE TEST

11.11.1 Take 14 Bottles of each head of filling machine and make one micro hole in each with 22 gauge needle and mark them with Permanent Marker.

11.11.2 Place these micro holed 14 Bottles in the each cycle of all three batches within the load

11.11.3 Record the result of each cycle in Performance Qualification Report.

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12.0 CHECKLIST OF ALL TESTS & CHECKS:

S.No.	NAME OF TEST OR CHECK
1.	Evaluation of Performance by Using First Batch
2.	Evaluation of Performance by Using Second Batch
3.	Evaluation of Performance by Using Third Batch

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 Leak Check Machine

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
ISO	:	International standard of organization
LTD	:	Limited
min	:	Minute
mm	:	Millimeter
No.	:	Number
QA	:	Quality Assurance
SOP	:	Standard operating procedure
VLT	:	Leak Check Machine
WHO	:	World Health Organization