PERFORMANCE QUALIFICATION PROTOCOL FOR SIX HEAD LOTION FILLING MACHINE

EQUIPMENT ID No.	
LOCATION	**FILLING LINE**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in Performance Qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

This Protocol is applicable for performance qualification of Six Head Lotion Filling Machine installed in Lotion Filling Line. The equipment is to be used for filling of bottle.

4.0 RESPONSIBILITY:

The Qualification team, 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, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification Protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.
Quality Control	• Review of Performance Qualification report. • Approval of report post approval.

5.0 EQUIPMENT DETAILS:

Equipment Name	Lotion Filling Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

It is a Fully Automatic Volumetric Filling machine. A Square fabricated out of S.S.316L imported sheet is provided at the center of filling section at both side of which 6equidistant piston- Cylinder assemblies are mounted. The volume in all the cylinders can be adjusted by adjusting the ring. Also, micro settings up to ½ ml can be done by turning the knob of square guide blocks in desired direction. The complete machine has been constructed in ASTM and AISI grade S.S.304/SS316 sheets/plates/rods. All product contact parts are in S.S.316 and filling bowl in S.S316L to make the machine chemically inert.

7.0 REASON FOR QUALIFICATION:

After completion of the Operational 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:

Filling Line.

9.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

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.

- SOP for Operation & Cleaning of Six Head lotion Filling Machine.
- SOP for Preventive Maintenance of Six Head lotion Filling Machine.

10.2 Training Record of Validation Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

11.0 TESTS & CHECKS:

11.1 Evaluation of Performance:

11.1.1 Objective:

To evaluate and to provide documented evidences for performance of equipment for proper filling of Bottles. The objective of the test is to determine whether the machine is able to filling the containers with desired level of Bulk.

11.1.2 Checks for machine:

- No. of Trial : 03 run
- Filling Machine Speed
- Fill Volume Variation
- Tank Level

11.2 Filling Machine Speed Optimization:

11.2.1 Method applied:

- The test should be carried out on each size of Bottle.
- Load the Bottles in six Head Lotion Filling machine.
- Switch "ON" the machine & Operate as per SOP.
- Set the machine speed (Bottle / Minute) through Stopwatch as per below table.

Bottle Size	Machine Speed (80 %)	Machine Speed (50 %)	Machine Speed (20 %)
10 ml	48 bottles / min.	30 bottles / min.	12 bottles / min.
100 ml	40 bottles / min.	25 bottles / min.	09 bottles / min.
200 ml	40 bottles / min.	25 bottles / min.	09 bottles / min.

- Start the machine with individual speed & count the Bottles after 10 minute for each speed.
- Repeat it three times at each speed.
- Final machine output shall be decided & verified after performing the test

11.2.2 Acceptance Criteria:

The machine should be smooth running at minimum and maximum speed.

11.3 Fill Volume Variation:

1. The test should be carried out for minimum & maximum strength.
2. Switch "ON" the machine & Operate as per respective SOP.
3. Perform the test by filling bulk at Minimum speed, optimized speed and maximum speed of machine with different tank level i.e. Full Tank level, Half tank level and 1/3rd Tank Level.

4. Perform the filling operation at 3 different speeds, for Min. and Max. Strength & check the fill variation of 05 bottles from each nozzle duly sampled at 3 cycles of the filling operation.
5. Collect Filled Bottles from the machine & measure filled bulk volume.

11.3.1 Acceptance Criteria:

The Fill Variation of Bottle should be up to ±1.0 %. of target volume.

11.4 Physical Test:

1. Collect the 02 tube from each Nozzle.
2. Check the tube physically i.e., Physical appearance, Leakage, foreign particles of Bottles.
3. Record the observation in Qualification Report.

11.4.1 Acceptance Criteria:

The Final product should be free from any Physical defect.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS	EXECUTED [Y/N]	COMMENT
Machine Speed Optimization		
Fill volume variation		
Physical Test		

13.0 REFERENCES:

- Validation Master Plan
- Schedule M: “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2: Good Manufacturing Practices and Inspection.

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED 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 operation as well as on performance of the machine & 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 operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

BMR	:	Batch Manufacturing Record
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Procedure
RH	:	Relative Humidity
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited