PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING MACHINE

EQUIPMENT ID No.	
LOCATION	**Filling and Sealing Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SIX HEAD LIQUID FILLING & SEALING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SIX HEAD LIQUID FILLING & SEALING MACHINE	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 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 Automatic Six Head Liquid Filling and Sealing machine installed in Filling & sealing Room.

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, Authorization of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Approval 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	Automatic Six Head Liquid Filling and Sealing Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Filling and Sealing Room

6.0 SYSTEM DESCRIPTION:

The Automatic Six Head Filling and Sealing machine is Divide into two Parts.

Filling Process:

The Six Head Automatic Filling machine Shall be Used to Filling by six head also work on Volumetric filling Principal, Whom fills with the help of vacuum and maintain the level of liquid in bottles on specified size and shape of bottles.

It is Comprises of Main Electric Panel with VFD, Relay, Operating panel, emergency switch & Push buttons, Nozzles Drive Assembly, Mechanical Stoppering System & Mechanical operation with motor gear box, cam, gears etc.

Sealing Process:

The Equipment shall be used to sealing with die by six head on specified size & shape of Bottle. Machines are equipped with cap feeder system for Continuous trouble free cap feeding.

It Comprises of Conveyer unit, Worm Assy, Star plate set sealing head Assy, Vibrator Bowl, Control Panel.

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 and Sealing Room Liquid 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 Automatic Six Head Liquid Filling and Sealing machine.
- SOP for Preventive Maintenance of Automatic Six Head Liquid Filling and Sealing 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
- Sealing Quality

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 Automatic Six Head Liquid Filling and Sealing 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 (100 %)	Machine Speed (50 %)	Machine Speed (20 %)
15 ml	80 bottles / min.	40 bottles / min.	16 bottles / min.
30 ml	60 bottles / min.	30 bottles / min.	12 bottles / min.
60 ml	60 bottles / min.	30 bottles / min.	12 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:

- The test should be carried out for minimum & maximum strength.
- Switch "ON" the machine & Operate as per respective SOP.
- Perform the test by filling bulk at Minimum speed, optimized speed and maximum speed of machine.
- Perform the filling operation at 3 different speeds, for each. Strength & check the fill variation of 05 bottles from each nozzle duly sampled at 3 cycles of the filling operation.
- 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:

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

11.4.1 Acceptance Criteria:

The Final product should be free from any Physical defect.

11.5 Sealing Quality:

- The test should be carried out for minimum & maximum strength.
- Switch "ON" the machine & Operate as per respective SOP.

- Perform the test by Sealing of Bottles at Minimum speed, optimized speed and maximum speed of machine.
- Collect the 2 Bottles from Each of sealing Head and check :
  - Proper Sealing (Leak Test)
  - Proper Teething
  - Breakage of Cap
  - Cut on Seals
  - Seal Rotation

11.5.1 Acceptance Criteria:

The Cap Sealing Quality should Complies with above Parameter.

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		
Sealing Quality		

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