PERFORMANCE QUALIFICATION PROTOCOL FOR AIRJET BOTTLE CLEANING MACHINE

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

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AIRJET BOTTLE CLEANING 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 (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 Manual Airjet Bottle Cleaning machine installed in Bottle Cleaning area.

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, and Approval of the Performance Qualification Protocol. • Co-ordination with, Production and Engineering to carryout Performance Qualification Activity. • Provide Training to qualification team.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• To provide the required utility and engineering support. • Responsible for trouble shooting (if occurred during execution). • To assist the qualification team. • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Airjet Bottle Cleaning Machine
Equipment ID.	
Manufacturer's Name	Bhavani Engineering
Location of Installation	Bottle Washing Area

6.0 SYSTEM DESCRIPTION:

The Automatic Airjet Bottle Air and Vacuum Cleaning Machine is compact unit totally made of SS structure with height adjustment legs, are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of washing for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles

PROCESS:

A Machine is inbuilt with Turntable for smooth transfer of round Bottle and suite is provided for noncircular Bottle to the Cleaning Section. This machine works with the principal of back pressure of container. Bottle feed by the Turntable or suit to reach to the star wheel, which transfers the Bottle to the cleaning section one after the. Bottle reaches to the cleaning section, air nozzles starts to flush the air inside towards the Bottle and simultaneously vacuum will suck the particles, disturbed by the air.

7.0 REASON FOR QUALIFICATION:

- New equipment installed.
- After completion of the Operation 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:

Bottle washing area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After Change of Location.
- Major Modification in Equipment

10.0 PRE-QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

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 Airjet Bottle Cleaning Machine.
- SOP for Preventive Maintenance of Airjet Bottle Cleaning 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 Machine Speed Optimization:

- The Test shall be performed on different- different size of Bottles.
- Load the bottles on the Conveyer belt.
- Switch “ON” the equipment & operate as per respective SOP.
- Run the Equipment at different speed.
- During running, check the Equipment speed synchronization
- After that, check the Cleaning of Bottles for minimum 20 Bottles.
- Said activity shall be performed initial stage, middle stage & end stage of equipment running.

11.2 AIR PRESSURE AND VACUUM CHALLENGE TEST :

11.2.1 Objective:

The objective of the test to determine the Effectiveness of Cleaning of bottle.

11.2.2 Scope:

The Scope of this test limited to the Bottle washing Area.

11.2.3 PROCEDURE:

- The test shall be performing on 100 bottles.
- Switch "ON" the machine & operate as per SOP.
- Set the air pressure between 1.5 to 2.5 Kg / cm^{2}.
- Set the vacuum Pressure 350 to 450 mmHg.
- Perform Cleaning test of bottle through generation of foreign particle, fabrics particle and paper piece.
- Place the on the nozzle neck into the chamber and apply the compressed air as preset.
- Apply the vacuum hold some time.
- Check Bottle visually none of any foreign particle, Fabric particle and paper piece should be present in the bottle.

11.3 ACCEPTANCE CRITERIA:

Foreign or any unwanted material should not observe visually.

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 Synchronization		
Air Pressure And Vacuum Challenge 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:

- Protocol Training record
- 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 shall 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 shall 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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Procedure
mm	:	Millimetre
Amp.	:	Amper
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited