



**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
BOTTLE WASHING MACHINE
LIQUID LINE**

EQUIPMENT ID. No.	
LOCATION	Washing Room
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	Nil



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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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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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 test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Bottle washing machine**, installed in the Washing room.
- This Protocol will define the methods and documentation used to qualify the Bottle washing machine for PQ.



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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	<ul style="list-style-type: none">• Preparation Review and Authorization of the Performance Qualification Protocol.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Protocol.• To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• Review of qualification protocol for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Bottle Washing machine
Equipment ID	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Washing Room

6.0 SYSTEM DESCRIPTION:

The Bottle Washing Machine finishes the procedures from bottle in feed, cleaning, external precision cleaning, internal precision cleaning, and bottle out feed. It adopts the ultrasonic cleaning, uses the recycled water and compressed air to clean the internal and external of bottles by a series of nozzles.

The washing machine consists of the following parts, such as

1. Water Tank -02 Nos.
2. Pump-02 Nos.
3. Control Panel
4. Indexing mechanism
5. Flow Control valve & Distribution Pipe lines

7.0 REASON FOR QUALIFICATION:

New Equipment Installed in washing area.

8.0 SITE OF STUDY:

Washing Room.

9.0 FREQUENCY OF QUALIFICATION:

- Once in 2 years \pm 1 month.
- After any major breakdown or after major modification.
- After Change of Location.



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10.0 PRE – QUALIFICATION REQUIREMENTS:

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

- Training of Performance Qualification Activity as Per Protocol.

11.0 TESTS AND CHECK

11.1 Evaluation of Performance:

The following test parameters to be fixed for the below mentioned Checks:

S.No.	Type of Bottle Size	Set Machine Speed	Set Compressed Air Pressure	Set Re-circulated Water Pressure	Set Purified Water Pressure	Set Hot Water Pressure
1.	15 ml PET Bottle	96 Bottles /minute	2 to 3 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²
2.	30 ml PET Bottle	96 Bottles/minute	2 to 3 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²
3.	60 ml Glass Bottle	96 Bottles/minute	2 to 3 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²
4.	15 ml Glass Bottle	96 Bottles/minute	2 to 3 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²	0.5 to 1.5 kg/cm ²

11.1.1 Objective:

To evaluate and to provide documented evidences for performance of equipment for proper washing of Bottles. The objective of the test is to determine whether the machine is able to clean the containers and eliminate the contamination (Chemical Substances) from the container itself. This test shall be carried out for different-different Bottle size, employed for washing.

11.1.2 Checks for machine:

- Chloride Content Test
- Glass Particle Test



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11.1.3 Test & Method:

11.1.3.1 CHLORIDE CONTENT TEST:

- Prepare 5 liters of 0.9 % w/v a Standard Sodium Chloride Solution.
- Take 06 Bottles for each and spike the sodium chloride solution for 15 & 30 ml & 60 ml Bottle. Take out the Bottles and dry the Bottles in hot air oven at 105°C for at least 1 hour.
- Load these marked Bottles along with similar sized Bottles in the feed SS guide channel and send to QC for further test.
- **Procedure Test for QC:** For the chloride identification test add 0.2 ml of 1.0M Silver Nitrate reagent plus 1ml dilute nitric acid in every Bottle and for Blank repeat the same procedure with good Bottles. Test passes if no opalescence or no turbidity is seen in all the Bottles including the blank also.
- Record the observation in Performance Qualification Report.

Acceptance criteria:

All individual Tested Bottles should be showing no turbidity or no opalescence after adding the above mentioned reagents.

11.1.3.2 GLASS PARTICLE TEST

- Take 06 Bottles for each and spike the Bottles with fine glass fragments; mark the Bottles by putting Teflon thread in the neck side.
- Load these marked Bottles along with similar sized Bottles in the in feed guide channel Collect one Bottle from each nozzle for Visual inspection after washing from the out feed conveyor. For Visual Inspection, add 12 ml purified water in to 15 ml Bottles, 24 ml purified water in to 30 ml Bottles, 48 ml purified water in to 60 ml Bottles
- Visually inspect the Bottles for the presence of any glass fragments against white background.
- Record the observation in Performance Qualification Report

Acceptance criteria:

The Bottles should be free from the glass particles (Visual inspection).



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11.1.4 Sampling Plan:

Batch No.	1 st Cycle		2 nd Cycle		3 rd Cycle		Total sampled Bottles	Justification for sampling
	Sampling Stage	No. of Sampled Bottles	Sampling Stage	No. of Sampled Bottles	Sampling Stage	No. of Sampled Bottles		
Chloride test	After Washing	06	After Washing	06	After Washing	06	18	To ensure proper washing of Bottles
Glass particle test	After Washing	06	After Washing	06	After Washing	06	18	To ensure proper washing of Bottles

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of performance using test for chloride.
- Verification of Glass Particle Test.

13.0 REFERENCES:

- EU GMP Annexure- 15.

14.0 DOCUMENTS TO BE ATTACHED:

- Raw data generated during testing.
- 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.



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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:

cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
EU	:	European Union
ID.	:	Identification
MOC	:	Material of Construction
NLT	:	Not Less Than
PQ	:	Performance Qualification
QA	:	Quality Assurance
QC	:	Quality Control
WHO	:	World Health Organization