



**PERFORMANCE QUALIFICATION REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

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

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



**PERFORMANCE QUALIFICATION REPORT
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PROTOCOL No.:

REPORT CONTENTS

S.No.	TITLE	PAGE No.
1.0	Report pre-approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment details	6
6.0	Pre-qualification requirement	6
7.0	Tests & checks	7-14
8.0	Checklist of all tests and checks	15
9.0	Documents to be attached	15
10.0	Non compliance	15
11.0	Deviation from pre-defined specification, if any	15
12.0	Change control, if any	16
13.0	Review inclusive of follow up action, if any	16
14.0	Conclusion	16
15.0	Recommendations	16
16.0	Abbreviations	17
17.0	Report post approval	18



**PERFORMANCE QUALIFICATION REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

1.0 REPORT PRE-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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**PERFORMANCE QUALIFICATION REPORT
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BOTTLE WASHING MACHINE**

PROTOCOL No.:

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 scope of this report is limited for Qualification of Bottle Washing machine installed in Bottle Washing Room Liquid Line.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.



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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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review Authorized and Compilation of the Performance Qualification Report.• 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 & Approval of Performance Qualification Report.• To co-ordinate and support Performance Re-Qualification Activity.• Post Approval of Performance qualification Report after execution.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis)
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• Post Approval of Performance qualification Report after execution.



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5.0 EQUIPMENT DETAILS:

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

6.0 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.



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PROTOCOL No.:

7.0 TESTS AND CHECKS:

7.1 Chloride Test for 15 ml glass bottle:

Bottle Size	15 ml Glass Bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Observation:

Trial-01		Trial-02		Trial-03	
Bottle No.	QC Result	Bottle No.	QC Result	Bottle No.	QC Result
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
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BOTTLE WASHING MACHINE**

PROTOCOL No.:

7.2 Chloride Test for 15 ml PET bottle:

Bottle Size	15 ml PET bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Observation:

Trial-01		Trial-02		Trial-03	
Bottle No.	QC Result	Bottle No.	QC Result	Bottle No.	QC Result
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
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PROTOCOL No.:

7.3 Chloride Test for 30 ml PET bottle:

Bottle Size	30 ml PET bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Observation:

Trial-01		Trial-02		Trial-03	
Bottle No.	QC Result	Bottle No.	QC Result	Bottle No.	QC Result
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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PROTOCOL No.:

7.4 Chloride Test for 60 ml Glass bottle:

Bottle Size	60 ml Glass bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Observation:

Trial-01		Trial-02		Trial-03	
Bottle No.	QC Result	Bottle No.	QC Result	Bottle No.	QC Result
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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PROTOCOL No.:

7.5 Glass Particle Test at 15 ml Glass bottle:

Bottle Size	15 ml Glass bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Observation:

Trial-01		Trial-02		Trial-03	
Bottle No.	Visual Observation	Bottle No.	Visual Observation	Bottle No.	Visual Observation
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

7.6 Glass Particle Test at 15 ml PET bottle:

Bottle Size	15 PET bottle ml
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Trial-01		Trial-02		Trial-03	
Bottle No.	Visual Observation	Bottle No.	Visual Observation	Bottle No.	Visual Observation
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
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BOTTLE WASHING MACHINE**

PROTOCOL No.:

7.7 Glass Particle Test at 30 ml PET bottle:

Bottle Size	30 PET bottle ml
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Trial-01		Trial-02		Trial-03	
Bottle No.	Visual Observation	Bottle No.	Visual Observation	Bottle No.	Visual Observation
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION REPORT
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PROTOCOL No.:

7.8 Glass Particle Test at 60 ml Glass bottle:

Bottle Size	60 ml Glass bottle
Date of Test	
Compressed Air Pressure	
Purified Water Pressure	
Circulated Water Pressure	
Hot Water Pressure	

Trial-01		Trial-02		Trial-03	
Bottle No.	Visual Observation	Bottle No.	Visual Observation	Bottle No.	Visual Observation
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	
4.		4.		4.	
5.		5.		5.	
6.		6.		6.	

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or checks	Executed (Yes/No)	Remarks	Verified by (QA) sign/date
Verification for Chloride Content Test			
Verification of glass particle Test			

Inference:

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**Reviewed By
Manager QA
Sign/Date:**

9.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

Asst.	:	Assistant
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
EU	:	European Union
FDA	:	Food and Drug Administration
IQ	:	Installation Qualification
Kg	:	Kilogram
Ltd.	:	Limited
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization



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17.0 REPORT POST 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)			