PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Washing & Sterilizing Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

REPORT CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

1.0 PRE – 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 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 Vial Washing Machine installed in Washing and Sterilizing Room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification. • 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.
Quality Control	• Review of Protocol. • Analytical Support (Microbiological Testing/Analysis)
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.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Washing Machine
Equipment	……
Manufacturer's Name	Ambica Pharma Machines Pvt. Ltd
Model	cGMP Model
Supplier's Name	Ambica Pharma Machines Pvt. Ltd
Location of Installation	Washing & Sterilization Room

6.0 PRE – QUALIFICATION REQUIREMENTS:

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.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Vial Washing Machine.
- SOP for Preventive Maintenance Vial Washing Machine.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	**Executed and approved Design Qualification document**				
2.	**Executed and approved Installation Qualification document**				
3.	**Executed and approved Operational Qualification document**				
4.	**PQ Protocol approved**				
5.	**SOP for Operation & Cleaning of Vial Washing Machine**				
6.	**SOP for Preventive Maintenance Vial Washing Machine**				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.2 Charcoal Test

Date of Test	
Vial Size	
Vial type	
Cycle	
Machine Speed	
Compressed Air Pressure	
WFI Pressure	
Re-circulated Water Pressure	
Purified Water Pressure	

Vial no.	Test	Observation			Analysed by Quality Control (Sign/Date)
		Initial	Middle	End	
1	VP				
2	VP				
3	VP				
4	VP				
5	VP				
6	VP				
7	VP				
8	VP				
9	VP				
10	VP				
11	VP				
12	VP				
13	VP				
14	VP				
15	VP				
16	VP				
17	VP				
18	VP				

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

Vial no.	Test	Observation			Analysed by Quality Control (Sign/Date)
		Initial	Middle	End	
19	VP				
20	VP				
	Average SVP for 20 Vials				

Acceptance criteria:

Visible particles (VP) **:** The vials should be free from visible particles.

Sub visible particles (SVP) **:** ≥10 µ: Not more than 6000

≥25 µ: Not more than 600

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.3 Chloride Test

Date of Test	
Vial Size	
Vial type	
Cycle	
Machine Speed	
Compressed Air Pressure	
WFI Pressure	
Re-circulated Water Pressure	
Purified Water Pressure	

Vial no.	Observation			Analysed by Quality Control (Sign/Date)
	Initial	Middle	End	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

Vial no.	Observation			Analysed by Quality Control (Sign/Date)
	Initial	Middle	End	
12				
13				
14				
15				
16				
17				
18				
19				
20				

Acceptance criteria: All individual washed vials should not show turbidity or opalescence after adding reagents.

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.4 Glass Particle Test

Date of Test	
Vial Size	
Vial type	
Cycle	
Machine Speed	
Compressed Air Pressure	
WFI Pressure	
Re-circulated Water Pressure	
Purified Water Pressure	

Vial no.	Observation			Analysed by Quality Control (Sign/Date)
	Initial	Middle	End	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

Vial no.	Observation			Analysed by Quality Control (Sign/Date)
	Initial	Middle	End	
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
Acceptance criteria: The vials should be free from the glass particles (Visual inspection).				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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
Verification of DQ, IQ & OQ & Other Documents		
Verification of Machine Performance		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of SOP's.
- 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:

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

17.0 POST 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)			