PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE

EQUIPMENT ID No.	
LOCATION	**'Q' BLOCK**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	

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PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE	PROTOCOL No.:

1.0 REPORT PRE- APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
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 Report is applicable for performance qualification of Airjet Bottle Cleaning machine installed in Bottle Washing 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 Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Provide Training to qualification team.
Production	• 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). • 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 Machine

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 PRE-QUALIFICATION REQUIREMENTS:

7.1 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.

7.2 SYSTEM PRE-REQUISITES:

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Airjet Bottle Cleaning machine has been prepared.

S. No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol approved			
2.	IQ Protocol approved			
3.	OQ Protocol approved			
4.	PQ Protocol approved			
5.	SOP for Operation & Cleaning of Airjet Cleaning Machine			
6.	SOP for Preventive Maintenance Airjet Cleaning Machine			

Checked By
Production
Sign / Date:_____

Verified By
Quality Assurance
Sign / Date: _____

Inference:……..……

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Reviewed By
Manager QA
Sign / Date: _____

8.0 TESTS & CHECKS:

8.1 Machine Speed Optimization:

8.1.1 Trial No.: 01:

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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Reviewed By
Manager QA
Sign / Date: _____

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE	PROTOCOL No.:

Trial No.: 02

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE	PROTOCOL No.:

8.1.2 Trial No.: 03

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date_____

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.2 Air Pressure Test :

8.2.1 Trial no.01:

Date of test		**Product name**	
Batch No.		**Pack Size**	

At Air Pressure 1.5 kg / cm^2 :

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.0 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.5 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

Checked By
Production
Sign / Date: : _____

Verified By
Quality Assurance
Sign / Date: : _____

Inference:……..……

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Reviewed By
Manager QA
Sign / Date: : _____

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE	PROTOCOL No.:

8.2.2 Trial No.02:

Date of test		Product name	
Batch No.		Pack Size	

At Air Pressure 1.5 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.0 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.5 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

Checked By
Production
Sign / Date:_____

Verified By
Quality Assurance
Sign / Date:_____

Inference:……..……

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Reviewed By
Manager QA
Sign / Date: _____

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE	PROTOCOL No.:

8.2.3 Trial No.03:

Date of test		Product name	
Batch No.		Pack Size	

At Air Pressure 1.5 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.0 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

At Air Pressure 2.5 kg / cm^2:

Date	Time	Qty. Taken	Observation			Checked By	Verified By
			Foreign Particle	Fabrics material	Paper Piece		

Checked By
Production
Sign / Date: _____

Verified By
Quality Assurance
Sign / Date: _____

Inference:……..……

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Reviewed By
Manager QA
Sign / Date: _____

9.0 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		
Air Pressure Test		

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

11.0 NON COMPLIANCE:

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12.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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13.0 CHANGE CONTROL, IF ANY:

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

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15.0 CONCLUSION:

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16.0 RECOMMENDATION:

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17.0 ABBREVIATIONS:

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

18.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTI ON)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			