INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AIRJET BOTTLE CLEANING MACHINE

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE-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 carry out the Installation Qualification of Air Jet Airjet Bottle Cleaning Machine used in Production, "The process conforming that an item of equipment, or other system, as currently installed, meets its design qualification".
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and maintain safely, effectively and consistently.

3.0 SCOPE:

- The Protocol covers all aspects of Installation Qualification of Air Jet Airjet Bottle Cleaning Machine used in Production.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as built drawing numbers of equipment drawing, P & ID and circuit diagram.

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 Installation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Installation Qualification. • To provide training on protocol to qualification team
Production	• Giving clearance to install the unit. • Execution of Installation Qualification activity. • Ensure that the equipment is installed as per protocol. • Monitoring of Installation Process..
Engineering	• To co–ordinate and support Installation Qualification activity. • Calibration of Process instruments. • Ensure that the equipment is installed as per protocol.

5.0 EQUIPMENT DETAILS:

Equipment Name	Airjet Bottle Cleaning Machine
Equipment ID	
Manufacturer's Name	
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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

All the documents should be available, complete and approved by respective authorities.

7.1 VERIFICATION OF DOCUMENTS:

S.No.	DESCRIPTION OF PRE-REQUISITE	COMPLETED (YES/NO)	CHECKED BY ENGINEERING SIGN/DATE	VERIFIED BY QA SIGN/DATE
1.	Verify that the DQ of the Airjet Bottle Cleaning Machine executed and approved. DQ Protocol Document No.			

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Leveling	Should be properly balanced and Leveled		
Edges of parts	The Metal parts should be properly grounded without any sharp edges		
Place of Installation	Bottle Washing Area 'Q' Block		
Room Condition	General working condition.		
Illumination in area	NLT 300 Lux inside the cubicle.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Production
Sign / Date: _____

Verified By
Quality Assurance
Sign / Date: _____

Inference:

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Reviewed By
Manager QA
Sign / Date: _____

8.2 EQUIPMENT VERIFICATION:

Before the equipment is operated, certain checks are to be completed:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Equipment : Airjet Bottle Cleaning Machine			
ELECTRICAL INSTALLATION:			
Electrical Supply	3 Phase Voltage- 230 V (± 6%) Frequency- 50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured		
All components in the panel are properly secured	Should be secured		
All terminals are tightened	Should be tightened		

Checked By
Production
Sign / Date:_____

Verified By
Quality Assurance
Sign / Date:_____

Inference:……..

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Reviewed By
Manager QA
Sign / Date:_____

8.3 INSTALLATION VERIFICATION:

The components of the system are inspected so as to verify that they are present and documented properly. Any incorrect installations or any deviations from specification are to be documented.

S.No.	VARIABLE	OBSERVATION	Checked By Engineering
1.	Check the proper mechanical installation of Air Jet Bottle Cleaning machine		
2.	Check the proper alignment of Airjet Bottle Cleaning Machine.		
3.	Check the proper electrical installation of Air Jet Airjet Bottle Cleaning Machine		
4.	Check the proper Mechanical Safety of Air Jet Bottle Cleaning machine		
5.	Check the proper service connection such as compressed air and Vacuum supply, and of Air Jet Airjet Bottle Cleaning Machine		
6.	Check the parts are working properly		
7.	Check the equipment is free from any defects		
8.	Check the finishing of Bottle contact parts		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

8.4 VERIFICATION OF MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS304
2.	Door Set	SS 304 (NO PAINTED SURFACE)
3.	Head	SS 304
4.	Star Plate	Nylon

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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

8.5 SAFETY TESTING:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Guards	Guards for all moving parts Should be provided For Motor safety		
Start On / Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

9.0 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-25: Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificates of MOC
- Calibration certificates

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:

cGMP	:	Current Good Manufacturing Practice
GMP	:	Good Manufacturing Practice
WHO	:	World Health Organization
P & ID	:	Piping and Instrumentation diagram
RH	:	Relative Humidity
^{o}C	:	Degree Centigrade
DQ	:	Design Qualification
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution Per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Kg	:	Kilogram
Hr.	:	Hour
MOC	:	Material of construction
FDA	:	Food and Drug Administration
EU	:	European Union
IQ	:	Installation Qualification
MCB	:	Miniature Circuit Breaker
V	:	Volts
IQ	:	Installation Qualification
Pvt.	:	Private
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 (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			