INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC AIRJET BOTTLE CLEANING MACHINE

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC 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
MANAGER (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Automatic Airjet Bottle Cleaning Machine. The purpose of Automatic Airjet Bottle Cleaning Machine is to provide a facility for cleaning of bottles with the help of 6 nos. air nozzles and continuous vacuum system.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP 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 be operated and maintained safely, effectively and consistently.

3.0 SCOPE:

- To verify the critical dimensions of the unit and record Serial Numbers/Model Number of critical components.
- 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.
- To Calibrate Temperature and Pressure Measurements of Control System, Recorder, Gauges and displays.

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	• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Automatic Airjet Bottle Cleaning Machine Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution

5.0 EQUIPMENT DETAILS:

Equipment Name	**Automatic Airjet Bottle Cleaning Machine**
Equipment ID	
Manufacturer's Name	
Supplier's Name	
Location of Installation	**Packing Area**
Purchase Order No. & Date	

6.0 SYSTEM DESCRIPTION:

The purpose of Automatic Airjet Bottle Cleaning Machine is to provide a facility for cleaning of bottles with the help of 6 nos. air nozzles and continuous vacuum system. The machine is inbuilt with Turntable for smooth transfer of bottles to the cleaning section. The bottles fed on the turntable reach to the bottle separator assembly through conveyor belt, which transfers the bottle in spaced manner to Pressing belt device. The bottles get inverted in mouth down position at the entrance of the pressing belt device. Here from the bottles held in mouth down position between pressing belt passes through cleaning section. Cleaning section is equipped with 6 nos. air nozzles and continuous vacuum system. While moving over the air nozzles, the pressurized and the ionized air is flushed inside the neck of the bottle and simultaneously vacuum suck the particles/ foreign particles, disturbed by the air. The bottle so cleaned moves to the inverter of the exit end of pressing belt device and get re-inverted in upright position and moves further for next operation.

The output speed is increased/ decreased by A.C. frequency drive.

7.0 CRITICAL VARIABLE TO BE MET:

7.1 PRE-QUALIFICATION REQUIREMENTS:

Verify that the DQ of the Automatic Airjet Bottle Cleaning Machine has been executed and approved.

S.No.	DOCUMENT NAME	DOCUMENT No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1.	DQ Protocol				

7.2 GENERAL CHECKS AND LOCATION SUITABILITY:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Equipment Should Be Properly Balanced & Leveled	Eng. / Production / QA to Certify		
All The Metal Parts Should Be Properly Grounded Without Any Sharp Edges.			
Welding of Joints Without Any Welding Burrs			
Place of Installation	Packing Area		
Room Condition	Temp.: NMT 25^0 C RH: NMT 55 %		
Illumination	NLT 300 Lux.		

Checked By
(Production)
(Sign/Date):……..

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

Inference:_____

_____

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

7.3 UTILITIES REQUIRED:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Electricity	• **Voltage:** 400 V • **Phases:** Three Phase • **Frequency:** 50 Hz		
Colour Indication of Button for Automatic Airjet Cleaning Machine	Shall be properly connected and identified		

Checked By
(Production)
(Sign/Date):……..

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

Inference:_____

_____

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

7.4 EQUIPMENT VERIFICATION:

7.4.1 Automatic Airjet Bottle Cleaning Machine specifications:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Equipment	Automatic Airjet Bottle Cleaning Machine		
Manufacturer	M/S Chamunda Pharma Tech Ahmedabad-382 445		
Main Motor and Gearbox	• Make: Bonfiglioli • 1.0 HP • 1400 RPM • 3 Phase • 415 V • 50 HZ		
Vibrator Unit	• 6 amp Vibrator card • 230 V		
Ionizer	SK Electronic		
Vacuum pump	Baldora(Chamunda make)		
Main MCB	• Make: Hager • No of pole: 4 • Ampere: 10A		
Relay	• Make: Telemecanique • Relay: 4		
Push Buttons	• Make: Telemecanique		
Air Pressure Controller	• Make: Baldora • Range: 2-5 Kg/cm^2		
Machine Dimensions	Length: 2250 mm Width: 650 mm 750 mm(From Turntable Side) Height 850 mm		

Checked By
(Production)
(Sign/Date):……..

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

Inference:_____

_____

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

7.5 INSTALLATION CHECKS:

S.No.	Specification	Observation	Observed By (Engineering) (Sign/Date)
1.	Check that major components are securely anchored and protected from shock.		
2.	Check that there is no observable physical damage.		
3.	Checks that there is sufficient room for servicing provided		
4.	All access parts are examined and cleaned of any default.		
5.	Walking access to roof mounted equipment provided.		
6.	Required electrical connections are tight weather proofed and grounded.		
7.	Wiring diagram glued or taped to inside section of control panel.		
8.	Equipment identification name plates are visible.		
9.	Units installed on foundation and secured in place as per manufacturer recommendations.		
10.	Check that equipment is properly balanced.		

Checked By
(Production)
(Sign/Date):……..

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

Inference:_____

_____

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

7.6 SAFETY:

Checks	Acceptance Criteria	Observation	Observed By Engineering (Sign/Date)
Well Embedded Equipment	For cGMP site layout		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors) and operator should be provided.		
Guards	Guards for all moving parts		
Motor overload relay – The switchgear shall trip if overloaded	Should be provided For Motor safety		
M.C.B off: To stop the process immediately	Should be provided For equipment and operator safety		

Checked By
(Production)
(Sign/Date):……..

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

Inference:_____

_____

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

8.0 REFERENCES:

The Principle References are as follows:

- Master Validation 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-2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

9.0 DOCUMENTS TO BE ATTACHED:

10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

11.0 CHANGE CONTROL, IF ANY:

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

13.0 CONCLUSION:

14.0 RECOMMENDATION:

15.0 PROTOCOL POST APPROVAL:

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
MANAGER (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
VICE PRESIDENT (QUALITY ASSURANCE)			

16.0 ABBREVIATIONS:

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
Amp.	:	Ampere
Ltd.	:	Limited
P & ID	:	Piping and Instrumentation Diagram
SS	:	Stainless Steel
DQ	:	Design Qualification
Eng.	:	Engineering
NMT	:	Not More Than
V	:	Volt
Hz	:	Hertz
PVC	:	Poly Vinyl Chloride
RPM	:	Revolution Per Minute
MOC	:	Material of Construction