OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
AIRJET BOTTLE CLEANING MACHINE

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AIRJET BOTTLE CLEANING 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 (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set of Acceptance Criteria and comply with relevant GMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the Operational features of Airjet Bottle Cleaning Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Equipment, Cleaning Procedure, start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The Protocol covers all the aspects of Operation Qualification for Airjet Bottle Cleaning Machine used.
- This Protocol defines the methods and documents to be used to qualify the Airjet Bottle Cleaning Machine for OQ.
- Successful completion of this Protocol will verify that the Airjet Bottle Cleaning Machine meets all acceptance criteria and is ready for Performance Qualification.

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, Approval and Compilation of the Operation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Operation Qualification
Production	• To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Monitoring of Operation Process.
Engineering	• Co-ordination, Execution and technical support in Airjet Bottle Cleaning Machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Airjet Bottle Cleaning Machine
Equipment ID.	
Manufacturer's Name	
Location of Installation	

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 PRODUCTION SIGN / DATE	VERIFIED BY QA SIGN / DATE
	Verify that the DQ of the single rotary tablet machine executed and approved.			
1.	DQ Protocol Document No.			
2.	IQ Protocol Document No.			
3.	**Draft SOP of Operation and Cleaning of Airjet Bottle Cleaning machine**			

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Test Instruments calibration Record:

Equipment/ Instruments name	Equipment/Instrument I.D.	Calibration on	Due on	Observed by Sign/date

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:……..

8.2 OPERATIONAL AND FUNCTIONAL CHECKS:

Operate the Airjet Bottle Cleaning Machine as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired

Operation	Acceptance criteria	Observation
Check correct working of Machine	The machine should be operational	
Operate the machine as per its SOP. Check for proper functioning.	These function are satisfactory	
Check working of pressure gauges/vacuum gauge	Displayed pressures are within the set limits.	
Removal of change parts and product changeover	As per changeover diagram.	
Removal of product contact parts and cleaning	As per changeover diagram.	
Start Machine	Machine should started by pressing the ON button.	
Stop Machine	Machine should stop by pressing the OFF button.	
Stirrer Motor ON	Press Stirrer motor OFF key Stirrer motor Should be ON.	
Vacuum Pump ON	Press Vacuum pump OFF key Vacuum pump Should be ON.	
Motor Overload	Machine stop immediately red light blows on tower lamp and "MOTOR OVER LOAD" alarm is generated on HMI.	

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

8.3 POWER FAILURE VERIFICATION:

ITEM	RESULTS	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions		

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

8.4 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		
Emergency Stop Alarm • Press emergency Stop switch	Machine stop immediately and red light blow ON tower Lamp.		

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-2: Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates of Instruments
- Any other Relevant Documents

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:

No.	:	Number
cGMP	:	Current Good Manufacturing Practice
GMP	:	Good Manufacturing Practice
WHO	:	World Health Organization
P & ID	:	Piping and Instrumentation diagram
SOP	:	Standard Operating Procedure
AC	:	Alternating Current
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution Per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Hr.	:	Hour
MOC	:	Material of construction
FDA	:	Food and Drug Administration
EU	:	European Union

17.0 POST APPROVAL:

INITIATED BY:

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DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

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