OPERATIONAL 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

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 verify that the equipment operates in accordance with the design and user requirement as defined by set acceptance criteria and complies with relevant cGMP Requirement
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the operational features of Automatic Airjet Bottle Cleaning Machine and to ensure that it produces desired Quality & rated output according to manufactures specification.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure, start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

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

4.0 RESPONSIBILITY:

The validation Group, comprising of a representative from each of 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 cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operation Qualification Protocol after Execution
Engineering	• Review of Operation Qualification. • To co-ordinate and support Operation Qualification Activity. • Calibration of Process Instruments.

The Operation of the Automatic Airjet Bottle Cleaning Machine is qualified by performing the prescribed tests and comparing the results against the given Acceptance Criteria, Exceptions are documented in the space provided and resolved prior to closing the OQ.

Upon completion of the above tests, the team will review the test results and indicate their Acceptance by signing the Authorization Page.

5.0 EQUIPMENT DETAILS:

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

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 PRE-QUALIFICATION REQUIREMENTS:

TEST EQUIPMENT CALIBRATION:

Verify that all critical instruments associated with the system will be in a calibrated state.

Review the calibration status for the test equipment to be utilized and record the calibration due dates in the table below. All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

Verify that the DQ/IQ of the Automatic Airjet Bottle Cleaning Machine has been executed and approved. Verify that the Operating and Cleaning SOP of the Automatic Airjet Bottle Cleaning Machine has been prepared.

S.No.	DOCUMENT NAME	DOCUMENT/SOP No.	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1.	DQ Protocol			
2.	IQ Protocol			
3.	Draft Operating Procedure SOP			
4.	Draft Cleaning Procedure SOP			

8.0 CRITICAL VARIABLE TO BE MET:

8.1 OPEARATIONAL AND FUNCTIONAL CHECKS:

Operate the Automatic Airjet Bottle Cleaning Machine as per Manufacture's Manual / SOP and check for the following functions of the Equipment. The Equipment should function as desired**:**

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Start Push Button	Machine Start		
Stop Push Button	Machine Stop		
Machine support	Able to support machine frame Structure from SS 304.		
MCB	MCB down machine shutdown immediately,		
Vacuum pump	Check the bag of the vacuum pump frequently for its cleanliness.		
Air Compressor	Range: 2-5 Kg/cm^2 if pressure is below the specified range the red button indicator will glow specifying low air pressure.		

Checked By
(Production)
(Sign/Date) :_____

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

Inference:_____

_____

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

8.2 SAFETY TESTING / INTERLOCKING:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Body earth	Body earth connection fitted.		
Motor Overload Relay	The switchgear shall trip if overloaded.		
ON/OFF Switch	To start and stop the process immediately.		
Overload Protection	Overload Protection devices are provided to stop the machine in the event of a jam or other malfunction.		

Checked By
(Production)
(Sign/Date) :_____

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

Inference:_____

_____

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

8.3 POWER FAILURE VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	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:_____

_____

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

9.0 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 Manufacturer, Version 4.0, December 2001.

10.0 DOCUMENT TO BE ATTACHED:

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

12.0 CHANGE CONTROL, IF ANY:

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

14.0 CONCLUSION:

15.0 RECCOMENDATION:

16.0 PROTOCOL POST APPROVAL:

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

17.0 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
IQ	:	Installation Qualification
OQ	:	Operational Qualification
EQ	:	Equipment