PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC AIRJET BOTTLE CLEANING MACHINE

EQUIPMENT ID / INSTRUMENT ID NO.	
LOCATION	**PACKING AREA**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL NO.	**NIL**

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

PROTOCOL CONTENT

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL 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
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To Provide documented evidence that the Automatic Airjet Bottle Cleaning Machine is performed as per the parameter defined in Operational Qualification and that it gives result as per the pre-determined 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.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Automatic Airjet Bottle Cleaning Machine.
- This Protocol will define the methods and documentation used to qualify Automatic Airjet Bottle Cleaning Machine for Performance Qualification.

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 Performance Qualification Protocol • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity • Monitoring of Performance Qualification.
Engineering	• Review of Protocol. • Calibration of all measuring Devices, • To Co-ordinate and support Performance Qualification Activity. • Operation of High Pressure Cleaner.
Production	• Review of Performance Qualification Protocol. • To Co-ordinate and support for execution of Performance Qualification study as per Protocol. • Post Approval of Performance Qualification Protocol after Execution

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 II**
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 REASON FOR QUALIFICATION:

After completion of the Operation Qualification of the Automatic Airjet Bottle Cleaning Machine, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing area.

9.0 FREQUENCY OF QUALIFICATION:

- After every two year
- After any major breakdown or after major modification.
- After Change of Location

10.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the Equipment, prepare final conclusion.

11.0 PRE-QUALIFICATION REQUIREMENTS:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to PQ commencing.

11.1 System Pre-requisites:

Verify that the DQ/IQ/OQ of 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.
1.	DQ Protocol	
2.	IQ Protocol	
3.	OQ Protocol	
4.	Operating Procedure SOP	
5.	Cleaning Procedure SOP	

12.0 TESTS AND CHECKS:

12.1 SPEED OF AUTOMATIC AIRJET BOTTLE CLEANING MACHINE:

12.1.1 Objective:

The objective of this test is to check the cleaning efficacy of Automatic Airjet Bottle Cleaning Machine.

12.1.2 Method:

- Start the Automatic Airjet Bottle Cleaning Machine and check the cleaning efficacy of Automatic Airjet Bottle Cleaning Machine.
- Place the product bottle pre-powdered with starch mixture on the conveyor belt.
- Run the machine and check the air pressure nozzle 6 in nos.
- Check the cleaning of the bottles visually.

12.2.4 Test Material / Equipment:

Starch

Bottle to be used in product.

13.0 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.

14.0 DOCUMENTS TO BE ATTACHED:

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

16.0 CHANGE CONTROL, IF ANY:

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

18.0 CONCLUSION:

19.0 RECOMMENDATION:

20.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
ID	:	Identification
SS	:	Stainless Steel
DQ	:	Design Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
RPM	:	Revolution Per Minute
ISPE	:	International Standard Pharmaceutical Engineering