PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM CLEANER

EQUIPMENT ID. No.	
LOCATION	**RM Dispensing Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	

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PROTOCOL CONTENTS

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1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in qualification protocol and that it gives result as per the predetermined 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 Vacuum Pump.

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 cum Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity • Monitoring of Performance Qualification.
Warehouse	• Review of Protocol cum Report. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review of Protocol cum Report To co-ordinate and support Performance Qualification Activity.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Vacuum Cleaner
Equipment	
Manufacturer's Name	
Model	
Sr. No.	
Supplier's Name	
Location of Installation	RM Dispensing Area

6.0 SYSTEM DESCRIPTION:

Vacuum Cleaner is a device that uses an air pump to create a partial vacuum to suck up dust and dirt, usually from floors, and optionally from other surfaces as well. The dirt is collected by in a dust bag, for later disposal. Vacuum Cleaner is used for removing the dust from the Floor, wall & material containers, The high vacuum suction remove most of the contamination dust from the outer surface of containers, Floor & Wall. The vacuum is created through the vacuum pump. The vacuum rate and the suction nozzles position have been decided in order to assure that the dust & fine particles are completely removed.

7.0 REASON FOR QUALIFICATION:

New Equipment.

8.0 SITE OF STUDY:

RM Dispensing Area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every five years ± one month.
- After any major breakdown or after major modification.

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10.0 PRE-QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	SOP for Operation, Cleaning and Maintenance of Vacuum Cleaner				

10.2 Training of Qualification Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

11.0 TESTS AND CHECKS:

11.1 EVALUATION OF AIR VELOCITY:

11.1.1 Objective:

- To verify the Air suction of Vacuum cleaner.

11.1.2 Equipment and Instruments

- Vane type Anemometer/ Pitot Tube and Manometer/Hot wire anemometer

11.1.3 Procedure:

- Measure airflow velocities from 6 inch away from the suction mouth of vacuum cleaner.
- Measurement time at should be at least 10-second duration and the five values should be recorded and calculate its average.

1.1.1 Acceptance Criteria:

- Air suction should NLT 30 FPM and measured at 6 inches below from suction mouth.

11.2 DUST CHALLENGE TEST.

11.2.1 Objective:

- To verify the Cleaning performance of vacuum cleaner.

11.2.2 Procedure:

Pre loads the vacuum cleaners with selected dust, this reflects the fact that in typical use. Vacuum cleaner are used with the bag partly filled (already weighed qty.). Then spread sand evenly into a area and vacuum it to a set pattern and speed, the collected sand is then weighed and recorded as a percentage of the sand applied and visually check the area and by rubbing the clean tissue paper on its surface. This test will be repeated thrice for each area.

1.1.2 Acceptance Criteria:

- The entire area should be free from dust/ sand particle.
- The difference should not more than 1%.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

S.No.	Name of Test or Check	Acceptance Criteria
1.	Air Velocity Measurement	Air suction should NLT 30 FPM
2.	Dust Challenge Test	Area should be free from dust particle

13.0 REFERENCES:

The Principle Reference is the following:

- 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificate of Anemometer

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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16.0 CHANGE CONTROL, IF ANY:

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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
EQ	:	Equipment
VCC	:	Vacuum Cleaner
NLT	:	Not less than
SS	:	Stainless steel
ID.	:	Identification