



**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
VACUUM CLEANER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>RM Dispensing Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES REPORT No.</b>	



**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**REPORT CONTENTS**

<b>S.No.</b>	<b>Title</b>	<b>Page No.</b>
<b>1.0</b>	<b>Report Pre-Approval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibility</b>	<b>5</b>
<b>5.0</b>	<b>Equipment Details</b>	<b>6</b>
<b>6.0</b>	<b>Pre-Qualification Requirements</b>	<b>7-8</b>
<b>7.0</b>	<b>Tests &amp; Checks</b>	<b>9-12</b>
<b>8.0</b>	<b>Checklist of all Tests &amp; Checks</b>	<b>13</b>
<b>9.0</b>	<b>Documents Attached</b>	<b>14</b>
<b>10.0</b>	<b>Non Compliance</b>	<b>14</b>
<b>11.0</b>	<b>Deviation From Pre-Defined Specification, If Any</b>	<b>14</b>
<b>12.0</b>	<b>Change Control, If Any</b>	<b>14</b>
<b>13.0</b>	<b>Review (Inclusive Of Follow Up Action, If Any )</b>	<b>15</b>
<b>14.0</b>	<b>Conclusion</b>	<b>15</b>
<b>15.0</b>	<b>Recommendation</b>	<b>15</b>
<b>16.0</b>	<b>Abbreviations</b>	<b>16</b>
<b>17.0</b>	<b>Report Post Approval</b>	<b>17</b>



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**1.0 REPORT PRE-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)			



**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification 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 report covers all aspects of Performance Qualification for the Vacuum Cleaner tunnel.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.



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## PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER

### 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 Report.

Departments	Responsibilities
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Performance Qualification Report.</li><li>• Protocol Training Record.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Warehouse</b>	<ul style="list-style-type: none"><li>• Review &amp; Approval of Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Approval of Report.</li><li>• Co-ordination, Execution and technical support in Area Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble shooting (if occurs during execution).</li></ul>



**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Vacuum Cleaner
<b>Equipment</b>	
<b>Manufacturer's Name</b>	
<b>Model</b>	
<b>Supplier's Name</b>	
<b>Location of Installation</b>	RM Dispensing Area

**6.0 PRE – QUALIFICATION REQUIREMENTS:**

**6.1 Verification of Documents:**

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

**6.2 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.



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**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**6.3 Calibration of all Components of System and Test Instruments:**

- Calibration of all the instruments used for Re-qualification should be mentioned along with Calibration Certificates.

S.No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date
1.						
2.						
3.						

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**



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**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**7.0 TESTS AND CHECKS:**

**7.1 AIR VELOCITY MEASUREMENT:**

**TEST INSTRUMENT DETAILS:**

<b>Instrument Name</b>	
<b>Make</b>	
<b>Model / Type</b>	
<b>Calibration Date</b>	
<b>Calibration Due Date</b>	
<b>Calibration Certificate Attached</b>	

**OBSERVATION AND RESULTS:**

S.No.	1	2	3	4	5	Average Air Velocity
<b>Air Velocity (Ft/min)</b>						

**Checked By:**  
**(Engineering)**  
**Sign & Date:**.....

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date:**.....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**





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**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**7.2 DUST CHALLENGE TEST:**

**Trial-I**

S.No.	Area	Status	Spread Qty. (in g)	Collected Qty. (in g)	%age	Remark
1.	Floor					
2.	Light Fixture					
3.	Balance					
4.	Table					
5.	Door					
6.	Container					
7.	Inner Side of RLAF					
8.	Dynamic Pass Box					
9.	Riser					

**Checked By**  
**(Warehouse)**  
**Sign & Date:**.....

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date:**.....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**



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**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**Trial-II**

S.No.	Area	Status	Spread Qty. (in g)	Collected Qty. (in g)	%age	Remark
1.	Floor					
2.	Light Fixture					
3.	Balance					
4.	Table					
5.	Door					
6.	Container					
7.	Inner Side of RLAF					
8.	Dynamic Pass Box					
9.	Riser					

**Checked By**  
**(Warehouse)**  
**Sign & Date:**.....

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date:**.....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**



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**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**Trial-III**

S.No.	Area	Status	Spread Qty. (in g)	Collected Qty. (in g)	%age	Remark
1.	Floor					
2.	Light Fixture					
3.	Balance					
4.	Table					
5.	Door					
6.	Container					
7.	Inner Side of RLAF					
8.	Dynamic Pass Box					
9.	Riser					

**Checked By**  
**(Warehouse)**  
**Sign & Date:.....**

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date:.....**

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**



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**8.0 CHECKLIST FOR TESTS & CHECKS:**

S.No.	Name of Test or Check	Execution (Yes/ No)	Remark	Verified By (Sign & Date)
1.	Air Velocity Measurement			
2.	Dust challenge test			

**Verified By:**  
**(Quality Assurance)**  
**Sign & Date:.....**

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**(Sign & Date: .....**



**PERFORMANCE QUALIFICATION REPORT FOR VACUUM CLEANER**

**9.0 DOCUMENTS ATTACHED:**

- Calibration Certificate of test Instruments.
- Any Other Relevant Documents.

**10.0 NON COMPLIANCE:**

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**11.0 DEVIATION FROM PRE-DEFINED 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
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
EQ	:	Equipment
VCC	:	Vacuum Cleaner
NLT	:	Not less than
SS	:	Stainless steel
ID.	:	Identification
g	:	gram



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**17.0 REPORT POST 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)			