OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

DE-BURRING MACHINE

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DE-BURRING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DE-BURRING MACHINE	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

 PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DE-BURRING MACHINE	PROTOCOL No.:

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Vibro type De- Dusting & De-burring and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Vibro type De- Dusting & De-burring **(Make: …….)** to be installed in the Compression.
- This Protocol will define the methods and documentation used to perform OQ activity the Vibro type De- Dusting & De-burring for OQ. Successful completion of this Protocol will verify that De-Duster meet all acceptance criteria and ready 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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in De-Duster Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vibro type De-dusting & De-burring
Equipment	……
Model	……
Manufacturer's Name	Chamunda Pharma Machinery Pvt. Ltd.
Supplier's Name	Chamunda Pharma Machinery Pvt. Ltd.
Location of Installation	Compression

6.0 SYSTEM DESCRIPTION:

Vibro De-dusting & De-burring machine is useful to De-dust tablets by airflow and to de-burring tablets by colloidation produced vibration.

A motorized Unbalance weight creates vibration. The De-dusting mounting unit, which is supported on springs, gets vibration, transfers vibration to the spiral assembly. Due to vibration the tablets, travel through spiral path up to end of the spiral path and discharged through outlet.

Machine is useful for any Type of tablets 4 to 25 mm diameter. The machine charging height is adjustable from 780 mm to 910 mm approx. and discharge height 630 mm to 760 mm approx.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for operating & Cleaning of De-Duster.
- SOP for Preventive Maintenance of De-Duster.
- Electrical circuits diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

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 OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By Sign & Date	Verified By Sign & Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	SOP for operation & Cleaning of De-Duster				
4.	SOP for Preventive Maintenance of De-Dusting & De-burring				

8.2 Operational and Functional Checks:

Operate the Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

S. No	Function	Operation	Acceptance criteria	Complies/Not Complies
1.	Power supply	Connect the power supply to the equipment	Display for electrical supply appears on the power control panel and Machine will ready for operation	
2.	Motor operation	Switch ON the equipment	Equipment starts operating and generates vibration	
3.	Movement of equipment	Move the equipment in all directions	Smooth & easy movement should be facilitated by castor wheels.	
4.	Regulating Knob	Increase vibration by rotating knob & vice versa.	Vibration should increase and decrease according to adjustment.	
5.	On – Off operation switch	Machine should start and stop as ON/OFF switch pressed.	Machine should start when ON switch pressed. Machine should stop when OFF switch pressed	

Checked By
Sign & Date: ……

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation (Complies/Not Complies)	Observed By 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
Sign & Date: ……

Inference:

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Reviewed By
Sign & Date: ……

9.0 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Copy of SOP's
- 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
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
ID.	:	Identification
mm	:	Millimeter
Pvt.	:	Private
Ltd.	:	Limited
DBM	:	De-berring Machine
GB	:	General block
cGMP	:	Current Good manufacturing Practise
GMP	:	Good manufacturing Practise
SOP	:	Standard Operating Procedure
WHO	:	World health organization
DQ	:	Design Qualification

17.0 POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			