INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DE-BURRING MACHINE

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

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DE-BURRING MACHINE

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)			

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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Vibro Type De- Dusting & De-burring.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Vibro Type De- Dusting & De-burring **(Make: Chamunda Pharma machinery Pvt. Ltd.)** to be installed in the Compression.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of De-Duster.

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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

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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 780mm to 910mm approx. and discharge height 630mm to 760mm approx.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P & ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Certificate of material of construction of components.

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 IQ Protocol cum report.

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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 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Complies/not Complies	Observed By Sign & Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Compression-, 'G' Block		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Sign & Date: ……

8.2 Equipment Verification:

Installation Checks	Acceptance Criteria		Complies/not Complies	Observed By Sign & Date
Equipment	Vibro Type De- Duster			
ELECTRICAL INSTALLATION:				
Electricity	Voltage	440 V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

Checked By
Sign & Date: ……

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8.3 Installation Checks:

S.No.	Specification	Complies/not Complies	Observed By Sign & Date
1.	Check the proper mechanical installation of Vibro Type De- Dusting.		
2.	Check the proper electrical installation of Vibro Type De- Dusting.		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Check that all parts are getting lubricated		

Checked By
Sign & Date: ……

8.4 MOC Verification List:

S.No.	Machine Parts	Acceptance Criteria	Complies/not Complies	Observed by Sign & Date
1.	Bowl	SS 316		
2.	Spiral	SS 316		
3.	Bowl Cover	SS 316		
4.	Bowl Support Ring	SS 304		
5.	Perforated Tray & Bottom Tray	SS 316		
6.	Bottom Tray Pipe	SS 316		
7.	Base	MS		

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8.5 EQUIPMENT VERIFICATION:

Name of The Component	Technical Specification	Complies/not Complies	Observed By Sign & Date
Equipment Name	Vibro Type De-dusting & De-burring		
Model	CPMVDB-150		
Specifications	All Contact parts in S.S.316		
De-dusting Distance	1.5 Meter (Approx.)		
Tablet output/Hour	2,00,000* (Approx.) (For ø8 mm Tablet)		
Height of Discharge	• Max.760mm(±10mm • Min 630 mm (±10mm)		
Height of Charging	• Max. 910 mm (±10mm) • Min. 780 mm(±10mm		
Maximum Tablet Dia.	25 mm		
Minimum Tablet Dia.	4 mm		
Over All Dimension	407mm×426mm×960mm (±10mm)		
Electric Motor	HP : 0.25 Power Supply : 440 V, 3 Phase AC, 50 Hz Motor Speed : 1440 RPM Type : Flange Mounted, NFLP Frame : 71 Make : Parth		
Castor Wheel	QTY. : 03 Nos.		
Starter	Make : BCH Range : 0.46 to 0.8A Model : AMLE -20		
MCB	2 Amp/Double Pole Make : Siemens (or equiv.)		
Height adjustment	780mm to 910mm approx.		
Electrical Supply	0.25 HP, 440 V, Single Phase, 50 Hz.		
Suction Points.	80 m^3/ hr. at 100 mm of W.C		
De dusting path	1.5 meter		
Charging passage size	Ø 70 mm (±1 mm)		
Discharging Passage Size	Ø 35 mm (±1 mm)		
Adjustable through time	25 to 60 sec		

Checked By
Sign & Date: ……

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8.6 SAFETY:

Checks	Acceptance Criteria	Complies/not Complies	Observed By Sign & Date
Well embedded equipment	For proper dust removal		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine		
Guard	Should be provided For Motor safety		
Start On/Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

Checked By
Sign & Date: ……

Inference:

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Reviewed By
Sign & Date: ……

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9.0 REFERENCES:

The Principle Reference is the following:

- 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates
- Operation and Maintenance Manual

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
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
IQ	:	Installation Qualification
Amp.	:	Ampere
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
ID.	:	Identification
mm	:	Millimeter
MCB	:	Miniature circuit break
CPM	:	Chamunda Pharma machinery

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17.0 POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

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