



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
DE-BURRING MACHINE**

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DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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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 prepare the Design Qualification document for De-Duster on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **De- Dusting (Make: Chamunda Pharma machine pvt.ltd.)**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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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	<ul style="list-style-type: none">• Initiation, Approval of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.➤ Details of utilities Required.➤ Identification of components for calibration➤ Material of construction of Product Contact Parts➤ Brief Process Description➤ Safety Features and Alarms• Review of Qualification Protocol after Execution.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution



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5.0 BRIEF EQUIPMENT 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on Requirement Specification prepared for manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Vibro type De-Duster/De-Burring Efficiency.	De-Duster Unit should be able to de-dust the tablets by airflow & to de-burring tablets by colloidation.	Process Requirement
Working: Working of Vibro type De-Duster Unit	De-Duster Unit works on the principle of vibration & facilitates the easy & efficient working during the course of the manufacturing operations.	Process Requirement



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7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Phase : 3 Phase Volt : 440 V Hz : 50 Hz	cGMP Requirement
Room Condition	Temp : 22±2 °C RH : 50±5 %	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Name of The Component	Technical Specification
1.	Equipment Name	Vibro type De-dusting & De-burring
2.	Model	CPMVDB-150
3.	Sr. No.
4.	Machine specification	All contact parts in S.S.316
5.	Tablet Output/Hour	2,00,000* (Approx.) (For ø8 mm dia. Tablet) (Output Depending upon Size and Shape)
6.	Height of Charging	<ul style="list-style-type: none">• Min 780 mm (±10mm)• Max.910 mm (±10mm)
7.	Height of Discharge	<ul style="list-style-type: none">• Min 680 mm (±10mm)• Max.760 mm (±10mm)
8.	Maximum Tablet Dia.	Ø 25 mm
9.	Minimum Tablet Dia.	Ø 4 mm
10.	De-dusting Distance	1.5 Meters (Approx.)
11.	Over all Dimension	407 mm×426 mm×960 mm



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12.	Product Contact Surface Area	6451.6 mm ²
13.	Main motor	HP : 0.25 RPM : 1440 RPM (± 10%) Power Supply : 415V, 3 phase AC, 50Hz. Type : Flange Mounted, Non FLP Frame : 71 Make : Parth
14.	Starter	Model : AMLE-20 Range : 0.46 to 0.80 A Make : BCH
15.	Hook Lifting	QTY. : 03 Nos. (Machine on Castor Wheel)
16.	Suction Points	80 m ³ / hr. at 100 mm of W.C

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Machine Parts	Acceptance Criteria
1.	Spiral Tray assembly	SS 316
2.	Bowl	SS 316
3.	Bowl supporting	SS 304
4.	Perforated tray & Bottom tray	SS 316
5.	Bottom Tray Pipe	SS 316
6.	Bowl Cover	SS 316
7.	Base Plate	M.S



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7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
Leveling And Balancing	Equipment should be properly balanced & leveled	Safety Requirement
Dust Generation Control	By Centralized Vacuum facility or Dust Extractor-150 CFM and at 70 mm W.C. Capacity (Client's Scope).	
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
Noise Level	Below 80 db	GMP & Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Vibro type Dusting & De-burring	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

Checked By
Sign & date:



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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification.
cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
GMP	:	Good Manufacturing Practice
DQ	:	Design qualification
kW	:	Kilo
QA	:	Quality Assurance Watt
HP	:	Horse Power
RPM	:	Revolution Per Minute
MOC	:	Material of Constriction
S.S	:	Stainless Steel
M.S	:	Mild Steel
PO	:	Purchase Order
Hr	:	Hour
mm	:	Millimeter
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
STD	:	Standard
Hz	:	Hertz
CPMPL	:	Chamunda Pharma Machine Pvt. Ltd
Pvt.	:	Privet
No.	:	Number
DBM	:	De-dusting machine



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			