



**PHARMA DEVILS**

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

**PROTOCOL No.:**

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

|                                |            |
|--------------------------------|------------|
| <b>DATE OF QUALIFICATION</b>   |            |
| <b>SUPERSEDES PROTOCOL No.</b> | <b>NIL</b> |



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**CONTENTS**

| <b>S.No.</b> | <b>TITLE</b>   | <b>PAGE No.</b> |
|--------------|--|-----------------|
| <b>1.0</b>   | <b>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>Brief Equipment Description</b>                           | <b>6</b>        |
| <b>6.0</b>   | <b>Equipment Specification</b>                               | <b>6</b>        |
| <b>7.0</b>   | <b>Critical Variables to be Met</b>                          | <b>6</b>        |
| <b>7.1</b>   | <b>Process/Product Parameters</b>                            | <b>7</b>        |
| <b>7.2</b>   | <b>Utility Requirement/Location Suitability</b>              | <b>7</b>        |
| <b>7.3</b>   | <b>Technical Specification/Key Design Features</b>           | <b>7</b>        |
| <b>7.4</b>   | <b>Material of Construction</b>                              | <b>8</b>        |
| <b>7.5</b>   | <b>Safety</b>  | <b>9</b>        |
| <b>7.6</b>   | <b>Vendor Selection</b>                                      | <b>9</b>        |
| <b>8.0</b>   | <b>Document to be Attached</b>                               | <b>10</b>       |
| <b>9.0</b>   | <b>Review (Inclusive of Follow Up Action, If Any)</b>        | <b>10</b>       |
| <b>10.0</b>  | <b>Any Change Made Against the Formally Agreed Parameter</b> | <b>10</b>       |
| <b>11.0</b>  | <b>Recommendation</b>  | <b>10</b>       |
| <b>12.0</b>  | <b>Abbreviations</b>   | <b>11</b>       |
| <b>13.0</b>  | <b>Reviewed by</b>   | <b>12</b>       |



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**1.0 PRE – APPROVAL:**

**PREPARED BY:**

| <b>DESIGNATION</b>                               | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|--|-------------|------------------|-------------|
| <b>OFFICER/EXECUTIVE<br/>(QUALITY ASSURANCE)</b> |             |                  |             |

**REVIEWED BY:**

| <b>DESIGNATION</b>                               | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|--|-------------|------------------|-------------|
| <b>OPERATING MANAGER<br/>(QUALITY ASSURANCE)</b> |             |                  |             |
| <b>HEAD<br/>(ENGINEERING)</b>                    |             |                  |             |
| <b>HEAD<br/>(PRODUCTION)</b>                     |             |                  |             |

**APPROVED BY:**

| <b>DESIGNATION</b>                  | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|-------------------------------------|-------------|------------------|-------------|
| <b>HEAD<br/>(QUALITY ASSURANCE)</b> |             |                  |             |



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**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 & ID's provided by Vendor shall be verified during Design Qualification.



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**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:

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



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**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. The manufacturer of equipment ensures complies with User Requirement Specification.

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS/PRODUCT PARAMETERS:**

| <b>Critical Variables</b>  | <b>Acceptance Criteria</b>   | <b>Reference</b>    |
|--|--|---------------------|
| <b>Application:</b><br>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 |
| <b>Working:</b><br>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 |



PHARMA DEVILS

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

**PROTOCOL No.:**

**7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

| Critical Variables   | Acceptance Criteria                           | Reference           |
|--|---|---------------------|
| Utility connections should be available as per the manufacturer's specification. |   |                     |
| <b>Electrical Supply</b>   | Phase : 3 Phase<br>Volt : 440 V<br>Hz : 50 Hz | cGMP Requirement    |
| <b>Room Condition</b>  | Temp : 22±2 °C<br>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.                      | 2V51/155  |
| 4.    | Machine specification        | All contact parts in S.S.316  |
| 5.    | Tablet Output/Hour           | 2,00,000* (Approx.) (For ø8 mm dia. Tablet)<br><br>(Output Depending upon Size and Shape)     |
| 6.    | Height of Charging           | <ul style="list-style-type: none"><li>Min 780 mm (±10mm)</li><li>Max.910 mm (±10mm)</li></ul> |
| 7.    | Height of Discharge          | <ul style="list-style-type: none"><li>Min 680 mm (±10mm)</li><li>Max.760 mm (±10mm)</li></ul> |
| 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  |
| 12.   | Product Contact Surface Area | 6451.6 mm <sup>2</sup>  |
| 13.   | Main motor                   | HP : 0.25   |



**PHARMA DEVILS**

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

**PROTOCOL No.:**

| S.No. | Name of the Component | Technical Specification   |
|-------|-----------------------|---|
|       |                       | RPM : 1440 RPM ( $\pm 10\%$ )<br>Power Supply : 415V, 3 phase AC, 50Hz.<br>Type : Flange Mounted, Non FLP<br>Frame : 71<br>Make : Parth |
| 14.   | Starter               | Model : AMLE-20<br>Range : 0.46 to 0.80 A<br>Make : BCH   |
| 15.   | Hook Lifting          | QTY. : 03 Nos.<br>(Machine on Castor Wheel)   |
| 16.   | Suction Points        | 80 m <sup>3</sup> / 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                 |





**PHARMA DEVILS**

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

**PROTOCOL No.:**

**7.5 SAFETY:**

| <b>Critical Variables</b>      | <b>Acceptance Criteria</b>   | <b>Reference</b>         |
|--------------------------------|--|--------------------------|
| 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:**

| <b>Critical Variables</b>   | <b>Acceptance Criteria</b>  | <b>Reference</b>    |
|---|---|---------------------|
| 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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**DESIGN QUALIFICATION PROTOCOL  
CUM REPORT  
FOR  
DE-BURRING MACHINE**

**PROTOCOL No.:**

**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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CUM REPORT  
FOR  
DE-BURRING MACHINE**

**PROTOCOL No.:**

**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                  |



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| <b>DESIGNATION</b>            | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|-------------------------------|-------------|------------------|-------------|
| <b>HEAD<br/>(ENGINEERING)</b> |             |                  |             |

| <b>DESIGNATION</b>           | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|------------------------------|-------------|------------------|-------------|
| <b>HEAD<br/>(PRODUCTION)</b> |             |                  |             |

| <b>DESIGNATION</b>                  | <b>NAME</b> | <b>SIGNATURE</b> | <b>DATE</b> |
|-------------------------------------|-------------|------------------|-------------|
| <b>HEAD<br/>(QUALITY ASSURANCE)</b> |             |                  |             |