



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

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**DATE OF QUALIFICATION**

**SUPERSEDES PROTOCOL No.**

**NIL**



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING 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>7</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>8</b>
<b>7.4</b>	<b>Material of Construction</b>	<b>11</b>
<b>7.5</b>	<b>Safety</b>	<b>11</b>
<b>7.6</b>	<b>Vendor Selection</b>	<b>12</b>
<b>8.0</b>	<b>Documents to be Attached</b>	<b>12</b>
<b>9.0</b>	<b>Review (Inclusive of Follow Up Action, If Any )</b>	<b>13</b>
<b>10.0</b>	<b>Any Changes Made Against the Formally Agreed Parameters</b>	<b>13</b>
<b>11.0</b>	<b>Recommendation</b>	<b>13</b>
<b>12.0</b>	<b>Abbreviations</b>	<b>14</b>
<b>13.0</b>	<b>Reviewed By</b>	<b>15</b>



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**1.0 PRE – APPROVAL:**

**INITIATED BY:**

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

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

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



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for **Tool Polishing Machine**.
- The equipment shall operate 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  
TOOL POLISHING 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:

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Preparation, Review and Approval 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> <li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li> <li>• Monitoring of Design Qualification Activity.</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>
<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</li> <li>➤ Identification of components for calibration</li> <li>➤ Material of construction of all components</li> <li>➤ System Description</li> <li>➤ Safety Features and Alarms</li> </ul> </li> <li>• Post Approval of Qualification Protocol cum report after Execution.</li> </ul>



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**5.0 BRIEF EQUIPMENT DESCRIPTION:**

Tool Polishing Machine is intermittent motion system driven by motor. These carry a tool holder where 45 punches & dies can be housed to carry the polishing function.

The polishing tank is filled with the defined quantity of the media (walnut shells) and the paste. The capacity of polishing tank is nearly 35 L where the media is loaded. The tool loading is simple and without any tools. On energizing the machine the tools start rotating and enter the tank bed having walnut powder. The time cycle is defined in the parameter settings the speeds is set as defined. On completion of the cycle the tool is made to rotate reverse to ensure that the walnut powder which is around the tool holder is emptied by centrifugal force and once this reaches the home position the rotation stops.

These tools after polishing will carry higher temperature and gloves shall be used to remove the same the same from the holder.

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specification is based on User Requirement Specification document is prepared. The manufacturer of equipment ensures complies with User Requirement Specification.



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS/PRODUCT PARAMETERS:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Tool polishing machine should be able to polish the surface of tablet punches and dies.	Tool polishing machine should be able to meet the criteria of polishing punches and dies leaving no rough surface.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Utility connections should be available as per the manufacturer's specification.		
<b>Source</b>	Power source : Voltage 230 V AC Control Source : 230 V AC Power of Main Motor : 1.5 KW	cGMP Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:**

<b>Components/ Parameters</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
<b>Gross Capacity</b>	135 punches per hour.	Design Requirement
<b>Machine Sr. No.</b>	.....	Design Requirement
<b>Polishing Motor</b>	Make : Bonfiglioli KW : 1.1 KW Volt : 220 V , 4.7 Amp Hz : 50 Phase : 3 RPM : 1390 Model no. : BN 90 S4	Design Requirement
<b>Gear Box</b>	Make : Bonfiglioli Type : F202H30FA20	Design Requirement
<b>MMI</b>	Make : Omron Model no. : NB 5Q- EW-00B 6500 Colour, Modbus	Design Requirement
<b>PLC</b>	Make : Omron Model no. : Sysmac CP Series, CP1E, CPU N30 IN 18 Pins & OUT 12 Pins	Design Requirement
<b>VFD For Polishing Motor</b>	Make : Omron Model no. : MX2 Series, 1 phase input, 3 phase output, 2 HP, Modbus	Design Requirement
<b>Sensor</b>	Make : Pepperl + Fuchs ( PNP TYPE, Operating voltage -24 VDC) Inductive Proximity Sensors Model : NBN4-12GM5—E2	Design Requirement
<b>Vertical Movement Actuator</b>	Make : Mecvel Model : ALF 3-F Stroke : 350 mm Speed : 14 mm/s Motor : 24 V DC	Design Requirement





PHARMA DEVILS

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

<b>Components/ Parameters</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
<b>Disc Speed</b>	RPM : 15 to 70 RPM	Design Requirement
<b>Polishing Tank Volume</b>	Capacity : 35 L	Design Requirement
<b>Bought out item</b>	<b>EMC Line Filter</b> Make : Elcom Quantity : 1 Specification : 250 VAC, 50 Hz, 10 A Model no. : EP 660-10 <b>Surge Suppressor</b> Make : Phoenix Contact Quantity : 1 <b>Earthing bus bar</b> Quantity : 1 MOC : Brass/ SS <b>8 Channel Relay Card</b> Make : Omron Quantity : 1 Specification : Coil Voltage= 24 V DC <b>VFD Drive</b> Make : Omron Quantity : 1 Specification : 1 Phase Input, 3 Phase Output, 2 HP, Modbus Model no. : SYSDRIVE MX2 <b>SMPS</b> Make : Mean Well Quantity : 1 Specification : I/P- 230 V AC, O/P- 24 V DC 4.3 Amp Model no. : S – 201 -24: D33100 <b>MMI DISPLAY</b>	Design Requirement



PHARMA DEVILS

DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE

PROTOCOL No.:

Components/ Parameters	Acceptance Criteria	Reference
	Make : Omron Quantity : 1 Specification : 5.7” Model no. : 5Q – EW-00B	
	<b>MCB</b> Make : Siemens Quantity : 1 Specification : 2 Pole, 10 Amp Model no. : 5 SQ22	
	<b>Safety switch</b> Make : Pizzato Quantity : 1 Model no. : FR 693	
	<b>Inductive Proximity Switch</b> Make : PEPPRL + FUCHS Quantity : 2 Specification : Cylinder DC 3 Wire Type 10- 30 V DC, 200 mA Model no. : NBN4-12GM50- E2	
	<b>Alarm Indicator</b> Make : Banner Quantity : 1 Specification : 18 to 30 V DC, 40 mA max./ LED Colour ( green, red, yellow) pulsed 75 db. Model no. : K50LGRA2YP	
	<b>Isolator switch</b> Make : Salzer Quantity : 1 Specification : 18 to 30 V DC, 40 mA max./ LED Colour (green, red, yellow) pulsed 75 db. Model no. : K50L GRA A 2YP	



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
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TOOL POLISHING MACHINE**

**PROTOCOL No.:**

<b>Components/ Parameters</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
	<p><b>Contact element</b> Make : Teknic Quantity : 1</p> <p><b>Emergency</b> Make : Teknic Quantity : 1 Specification : Red Button With Yellow Ring</p>	



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**7.4 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of Construction	References
1.	Polishing Tank	SS 304	Process Requirement
2.	Base Frame	SS 304	Process Requirement
3.	Guard Frame Body	Aluminum Section	Process Requirement
4.	Machine body frame	Aluminum Section	Process Requirement
5.	Machine body cover	Acrylic	Process Requirement
6.	Control panel frame	SS 304	Process Requirement

**7.5 SAFETY:**

Critical Variables	Acceptance Criteria	Reference
<b>Moving Parts</b>	All moving part are covered and guarded.	Safety Requirement
<b>Emergency Stop</b>	Easy assessable location for operator.	Safety Requirement
<b>Earthing</b>	Proper earthing is provided to the machine body.	Safety Requirement
<b>Noise Levels</b>	Should not exceed 80 decibels averaged over source operative period at distance of 1 mtr. From the noise source at a height of 1.5 mtr.	Safety Requirement
<b>Electrical Safety</b>	Overload relay and fuses are incorporated at the necessary location in the circuit.	Safety Requirement
<b>Safety Inter Lock</b>	All safety interlocks are correctly incorporated as per the process flow and inter- linkages.	Safety Requirement
<b>Alarms</b>	Door open , Emergency alarm produced during these situations for safety purpose	Safety Requirement



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
TOOL POLISHING MACHINE**

**PROTOCOL No.:**

**8.0 VENDOR SELECTION:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Reference</b>
<b>Selection of Vendor for supplying the Tool Polishing Machine</b>	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)	Selection of Vendor is done as per the procedure of Vendor Approval and all the relevant aspects including Vendor background, Technical knowhow, Quality standards, Inspection of site, costing, feedback from market considered prior to Vendor selection.	Process Requirement

**Reference:** (1) The equipment shall confirm to the specifications and requirement.  
(2) Operation and service manual for Tool Polishing Machine.

**9.0 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.





**PHARMA DEVILS**

**DESIGN QUALIFICATION  
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FOR  
TOOL POLISHING MACHINE**

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**13.0 ABBREVIATIONS:**

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
QA	:	Quality Assurance
PO	:	Purchase Order
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
db	:	Decibel
RH	:	Relative Humidity
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo watt
SS	:	Stainless Steel
PLC	:	Programmable Logical Control
ID.	:	Identification
Ltrs	:	Liters
MCB	:	Miniature Circuit Break
HMI	:	Human Machine Interface



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**14.0 REVIEWED BY:**

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

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

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