



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

EQUIPMENT ID. No.	
LOCATION	Die Punch Store Room
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To carry out the Installation Qualification of Tool Polishing Machine.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment Safely, Effectively and Consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Tool Polishing Machine (Make- Parle Elizabeth, Capacity-135 Punch/hr)** to be installed in the Die Punch Store Room.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following department shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Approval, Compilation and Authorization of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.
Production	<ul style="list-style-type: none">• 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 cum report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum report after Execution



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5.0 EQUIPMENT DETAILS:

Equipment Name	Tool Polishing Machine
Equipment ID.	
Manufacturer's Name	Parle Elizabeth
Supplier's Name	Parle Elizabeth
Location of Installation	Die Punch Store Room

6.0 SYSTEM 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 35L 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.



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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.
- Calibration Certificate of Components.
- 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.

7.1.2 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation	Observed by (Engineering) Sign/ Date
1.	Check the proper mechanical installation of Tool Polishing Machine		
2.	Check the proper electrical installation of Tool Polishing Machine		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		

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8.2 General Checks & Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled.		
Edges of Parts	Metal edges should be properly Rounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Die Punch Storage Room		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		
Machine Inspection	Ensure that all parts are present and not damaged.		
Electrical component verification	Ensure that the electrical components match to the descriptions in DQ.		

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8.3 MOC Verification List:

S.No.	Component	MOC	Observation	Observed by (Engineering) Sign/Date
1.	Polishing Tank	SS 304		
2.	Base Frame	SS 304		
3.	Guard Frame Body	Aluminum Section		
4.	Machine body frame	Aluminum Section		
5.	Machine body cover	Acrylic		
6.	Control panel frame	SS 304		

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8.4 Safety Label Verification:

Safety Label	Location	Available (Yes/No)	Observed By (Engineering) Sign/Date
Caution label	Electrical panel cover on main machine and on Accumulator Electrical Enclosure, Terminal Boxes Motor		
To open only when stopped	Moving components and drives enclosures for safety purpose.		
EMG stop	Control Panel, Emergency Stop		
Language Selection	Control panel		
Main Menu, Auto Operation, Manual Operation, Set Up, Recipe, Input, Output, Alarm, Alarm history, Auto Rotation	Control panel		

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8.5 Equipment Verification:

8.5.1 Technical Specifications:

Components/ Parameters	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
Gross Capacity	135 punches per hour.		
Machine Sr. No.	TP ECO-003		
Polishing Motor	Make : Bonfiglioli KW : 1.1 KW Volt : 220 V , 4.7 Amp Hz : 50 Phase : 3 RPM : 1390 Model no. : BN 90 S4		
Gear Box	Make : Bonfiglioli Type : F202H30FA20		
MMI	Make : Omron Model no. : NB 5Q- EW-00B 6500 Colour, Modbus		
PLC	Make : Omron Model no. : Sysmac CP Series, CP1E, CPU N30 IN 18 Pins & OUT 12 Pins		
VFD For Polishing Motor	Make : Omron Model no. : MX2 Series, 1 phase input, 3 phase output, 2 HP, Modbus		
Sensor	Make : Pepperl + Fuchs (PNP TYPE, Operating voltage -24 VDC) Inductive Proximity Sensors Model : NBN4-12GM5—E2		
Vertical Movement	Make : Mecvel Model : ALF 3-F		



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Components/ Parameters	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
Actuator	Stroke : 350 mm Speed : 14 mm/s Motor : 24 V DC		
Disc Speed	RPM : 15 to 70 RPM		
Polishing Tank Volume	Capacity : 35 L		
Bought out item	EMC Line Filter Make : Elcom Quantity : 1 Specification : 250 VAC, 50 Hz, 10 A Model no. : EP 660-10 Surge Suppressor Make : Phoenix Contact Quantity : 1 Earthing bus bar Quantity : 1 MOC : Brass/ SS 8 Channel Relay Card Make : Omron Quantity : 1 Specification : Coil Voltage= 24 V DC VFD Drive Make : Omron Quantity : 1 Specification : 1 Phase Input, 3 Phase Output, 2 HP, Modbus Model no. :SYSDRIVE MX2 SMPS Make : Mean Well		



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Components/ Parameters	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
	Quantity : 1 Specification : I/P- 230 VAC, O/P- 24 V DC 4.3 Amp Model no. :S – 201 -24: D33100 MMI DISPLAY Make : Omron Quantity : 1 Specification : 5.7” Model no. : 5Q – EW-00B MCB Make : Siemens Quantity : 1 Specification : 2 Pole, 10 Amp Model no. : 5 SQ22 Safety switch Make : Pizzato Quantity : 1 Model no. : FR 693 Inductive Proximity Switch Make : PEPPRL + FUCHS Quantity : 2 Specification : Cylinder DC 3 Wire Type 10- 30 V DC, 200 mA Model no. :NBN4-12GM50- E2 Alarm Indicator Make : Banner Quantity : 1 Specification : 18 to 30 V DC,		



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Components/ Parameters	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
	40 mA max./ LED Colour (green, red, yellow) pulsed 75 db. Model no. :K50LGRA2YP Isolator switch 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 Contact element Make : Teknic Quantity : 1 Emergency Make : Teknic Quantity : 1 Specification : Red Button With Yellow Ring		

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Sign/Date:



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8.6 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Identification and verification of major and sub components of Tool Polishing Machine		
2.	Verification of system utility requirements.		
3.	Check that all bolts are properly tightened.		
4.	Ensure all Electric connections done properly.		
5.	Ensure all mechanical adjustment.		
6.	Check that all Pneumatic connections are properly fitted.		

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8.7 Safety:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors) and operator should be provided.		
MCB for overload Trip	Should be provided for equipment safety.		
Emergency off: To stop the process immediately	Should be provided For equipment and operator safety		

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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.

The following references are used for addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

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



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16.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
EU	:	European Union
SS	:	Stainless Steel
HP	:	Horse Power
V	:	Volt
Hz	:	Hertz
QA	:	Quality Assurance
IQ	:	Installation Qualification
No.	:	Number
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo gram
MCB	:	Miniature Circuit Break
HMI	:	Human Machine Interface
Id	:	Inner diameter



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17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			