PERFORMANCE QUALIFICATION

PROTOCOL

FOR

TOOL POLISHING MACHINE

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

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR TOOL POLISHING MACHINE

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for Tool Polishing Machine **(Make-Parle Elizabeth)** installed in the **Die Punch Store Room.**
- This Protocol will define the methods and documentation used to qualify the Tool Polishing Machine for PQ.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Review and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Approval of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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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 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 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.

7.0 REASON FOR QUALIFICATION:

- New equipment in Die Punch Store Room Section.
- After completion of the Operational Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Die Punch Store Room.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every five year $\pm$ 1 month.
- After any major breakdown or after major modification.
- After Change of Location.

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10.0 PRE - QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the Performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Tool Polishing Machine.

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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

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

11.0 TESTS AND CHECKS:

11.1 Evaluation of Performance Using cleaned Die and Punch

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Tool Polishing Machine is performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of milled products.

11.1.1 Method:

- Operate the machine as per SOP: **OPERATION AND CLEANING OF TABLET PUNCH AND DIES POLISHING MACHINE**.
- Record the time for operation.
- During and after the completion of polishing operation following tests and checks shall be performed:
  1. Polishing Output of Tool Polishing Machine.

2. Appearance of Polished Die and Punch.
3. Presence of black particles

11.1.2 Tests & Checks:

1. **Polishing Output of Tool Polishing Machine**

Method:

- Fill the polishing container with 35 kg ± 200 gm Walnut Shells granules.
- Set parameters on HMI Rotation 45,55,60 RPM, Time 40,30,20 minutes
- Quantity of Die and Punch is loaded in Tool Polishing Machine.
- Polishing is performed and operation time is recorded.

Acceptance criteria:

- Machine output is recorded.

2. **Appearance of Polished Die and Punch**

Method:

- Perform visual check for appearance of compressed tablets by using Polished Die and Punch.
- Perform checks at initial, middle and at the end of operation of three batches.

Acceptance criteria:

- Appearance of compressed tablets should be uniform.

3. **Presence of Black Particles**

Method:

- Perform visual check for presence of black particles in Polished Die and Punch.
- Perform checks at initial, middle and at the end of three batch operation.

Acceptance criteria:

- Black particle should be absent.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of performance using unpolished Die and Punch.

13.0 REFERENCES:

The Principle References are as 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
NLT	:	Not Less Than