



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	7
8.0	Critical Variables to be Met	8
9.0	References	14
10.0	Documents to be Attached	14
11.0	Deviation from Pre-Defined Specification, If Any	15
12.0	Change Control, If Any	15
13.0	Review (Inclusive of follow up action, If Any)	15
14.0	Conclusion	16
15.0	Recommendation	16
16.0	Abbreviations	17
17.0	Post Approval	18



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and comply with cGMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the operational features of Tool Polishing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure and Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Tool Polishing Machine (Make- Parle Elizabeth, Capacity-135 Punch/hr)** installed in Die Punch Store Room.
- This Protocol will define the methods and documentation used to perform operational activity the Tool Polishing Machine for OQ. Successful completion of this Protocol will verify that Tool Polishing Machine meet all acceptance criteria and ready for Performance Qualification.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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 Compilation and Authorization of the Operation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Operation Qualification.• Monitoring of Operation Process.
Production	<ul style="list-style-type: none">• Review of Operation Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operation Qualification study as per Protocol.• Post Approval of Operation Qualification Protocol cum report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operation Qualification.• To co-ordinate and support Operation Qualification Activity.• Calibration of Process Instruments.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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.

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 OQ Protocol cum report.

7.1.2 Acceptance Criteria:

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



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Documents Verification:

S.No.	Document Name	Document /SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for Operation and Cleaning of Tablet Punch and Dies Polishing Machine				

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
Sign/Date:

Inference:

.....
.....
.....
.....
.....

Reviewed By (Manager QA)
Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All equipment/instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/ Instrument ID.	Calibration Done On	Calibration Due On	Observed By Sign/Date

**Checked By
(Production)**
Sign/Date:

**Verified By
(Quality Assurance)**
Sign/Date:

Inference:

.....
.....
.....
.....
.....

**Reviewed By
(Manager QA)**
Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.3 Operational and Functional Checks:

Operate the Tool Polishing Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Parameter	Operation	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Tool Polishing Machine	Polish the tool using polishing paste at a set cycle.	Surface finish of tool gets improved after completion of cycle.		
E- stop push button	E- Stop push button for emergency stop during equipment processing.	Machine stop		
Operating range	Operate basic machine at : speed 10 -45 cycle/ min			

**Checked By
(Production)**

Sign/Date:

Inference:

.....

Verified By

(Quality Assurance)

Sign/Date:

Reviewed By

(Manager QA)

Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.4 Verification of fault indication on MMI:

Fault	Cause	Effect	Corrective action	Observed By (Engineering) Sign/Date
Emergency Stop Alarm	When the E-Stop push button is pressed.	Machine stops		
Door Open Alarm	When the Tool Polishing Assembly door is opened	Machine stop		
Add shining paste in the media.	When the time duration elapsed after last addition of the shining paste is become more than the set paste time duration parameter.	Machine continue sits running state but buzzer become on , red indicator start flashing		
Change the media	When the time duration elapsed after last changeover of the media is become more than the set media time duration parameter.	Machine continues its running state but buzzer become on , red indicator start flashing		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

.....

.....

.....

.....

.....

.....

Reviewed By
(Manager QA)
Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.5 Power Failure Verification:

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment should be stopped in a safe and secure condition.		
Restore electrical power to the system	The system should not be automatically restart whenever start through PLC.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

.....
.....
.....
.....
.....

**Reviewed By
(Manager QA)
Sign/Date:**



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

8.6 Emergency Operation Verification:

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Emergency STOP: <ul style="list-style-type: none"> Press Emergency Stop Push Button. Release Emergency Stop Push Button & Start the M/C through HMI. 	Operation of Equipment should be stopped.		
	Operation of Equipment should be started.		
With the Emergency Stop Pressed in, try to cause movement of an Operating function.	The Equipment should be inoperative.		

**Checked By
(Production)**
Sign/Date:

**Verified By
(Quality Assurance)**
Sign/Date:

Inference:

.....

.....

.....

.....

.....

**Reviewed By
(Manager QA)**
Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

11.0 DEVIATION FROM PRE - DEFINED SPECIFICATION IF, ANY:

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

12.0 CHANGE CONTROL, IF ANY:

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

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

.....
.....
.....
.....
.....
.....
.....
.....



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

16.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
OQ	:	Operational Qualification
Ltd.	:	Limited
DQ	:	Design Qualification
IQ	:	Installation Qualification
No.	:	Number
RMG	:	Rapid Mixer Granulator
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
Mm	:	Millimeter
MCB	:	Miniature Circuit Break
HMI	:	Human Machine Interface
Id	:	Inner diameter



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TOOL POLISHING MACHINE

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)			