OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

CAPSULE POLISHING MACHINE &

UNFILLED CAPSULE SEPARATOR

EQUIPMENT ID. No.	
LOCATION	**Capsule Filling**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CAPSULE POLISHING MACHINE & UNFILLED CAPSULE SEPARATOR	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CAPSULE POLISHING MACHINE & UNFILLED CAPSULE SEPARATOR	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Capsule Polishing Machine & Unfilled Capsule Separator and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Startup & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Capsule Polishing Machine & Unfilled Capsule Separator installed in the Capsule Filling.
- This Protocol will define the methods and documentation used to perform OQ activity the Capsule Polishing Machine & Unfilled Capsule Separator for OQ. Successful completion of this Protocol will verify that Compression Machine meet all acceptance criteria and ready 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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval and Compilation of the OQ Protocol cum Report. • Co-ordination with Production and Engineering to carryout OQ. • Monitoring of Operational Qualification Activity.
Production	• Review, Pre & Post Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol.
Engineering	• Review, Pre & Post Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Capsule Polishing Machine & Unfilled Capsule Separator Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Capsule Polishing Machine & Unfilled Capsule Separator
Equipment	
Manufacturer's Name	
Model	DPM & UCS
Supplier's Name	
Location of Installation	Capsule Filling

6.0 SYSTEM DESCRIPTION:

The entire equipment comprises of the following units:

- **Capsule Polishing Unit**
  - The capsule polishing machine consists of the polishing brush in the Teflon net assembly. The assembly is then enclosed inside the perforated SS cylindrical drum.
  - The perforated drum is placed on the tray like structure for the collecting the powder generated during the polishing of the capsules.
  - The powder from the tray is sucked by means of the vacuum blower into the de-dusting tank.
  - The polishing assembly is placed at an inclined position & has the spring that directs the capsules to the outlet. During this process, the capsules get rubbed against the brush thereby polishing the capsules.
  - The polishing assembly is driven by means of 0.5 HP electric motor through timing belt and pulley.
  - A variable frequency drive is provided to vary the RPM of the polishing brush.
  - The electrical control panel for the polishing unit such as MCB, VFD etc. is placed in the common SS control panel.
- **Unfilled Capsule Separator Unit**
  - The unfilled capsule separator unit consists of SS hopper assembly with outlet chutes at different heights.
  - The unfilled capsule separator unit works on the principle of the air flow that has the varying effects on the unfilled capsules and properly filled capsules.
  - The required airflow is developed by means of single phase blower and the airflow is directed in the circular fashion by means of a fixed impeller.

- The capsules directed towards the periphery of the airflow by means of capsule guide pipe placed centrally on the impeller.
- The circular direction of the airflow imparts clockwise motion on the capsules. The filled or unfilled capsule will rotate at a higher orbit and the properly filled capsules will rotate at the lower orbit.
- The two outlet chutes are provided at different heights for collecting the capsule rotating at different orbits thus separating the unfilled capsules from the properly filled capsules.
- A dimmer is provided to vary the voltage of the blower thereby the airflow required for lifting the capsules. The airflow is adjusted depending on the filled weight of the capsules.
- The electrical control for the separator unit is provided in the common SS electrical control panel.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report.
- IQ Protocol Cum Report.
- Draft SOP for operating & Cleaning of Empty capsule Sorter Elevator.
- Draft SOP for Preventive Maintenance of Empty capsule Sorter Elevator.
- Technical specification of equipment.

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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 VERIFICATION OF DOCUMENTS:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	DQ Protocol Cum Report		
2.	IQ Protocol Cum Report		
3.	Draft SOP for operating & Capsule Polishing Machine & Unfilled Capsule Separator		
4.	Draft SOP for preventive maintenance of Capsule Polishing Machine & Unfilled Capsule Separator		

Checked By
Sign & Date:

Verified By
Sign & Date:

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 On	Due On	Observed By Sign & Date

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3 FUNCTIONAL VERIFICATION OF VARIOUS OPERATIONAL AND FUNCTIONALITY CHECKS:

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

8.3.1 POLISHING MOTOR FUNCTIONALITY TEST:

Operational Checks	Acceptance Criteria	Observation
Select the manual mode by operating the auto / manual selector switch and then switch ON the polishing motor by operating its selector switch	Polishing motor & Air Dispalcement Unitblower starts	
By rotating the VFD Knob in Clockwise direction	The Speed of the Polishing Motor will increase	
By rotating the VFD Knob in Anti clockwise direction	The Speed of the Polishing Motor will decrease	
Switch OFF the polishing motor by operating its selector switch	Polishing motor & Air Displacement Unit blower stops	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3.2 UCS BLOWER FUNCTIONALITY TEST

Operational Checks	Acceptance Criteria	Observation
Select the manual mode by operating the auto / manual operation and then switch on the blower by operating its selector switch	UCS blower will starts	
Turn the dimmer knob in clockwise direction	The air blow voltage increase	
Turn the dimmer knob in anticlockwise direction	The air blow voltage decreases	
Switch OFF the UCS blower by operating its selector switch	UCS blower stops	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3.3 AUTO / MANUAL FUNCTIONALITY TEST:

Operational Checks	Acceptance Criteria	Observation
Select the manual mode by operating its selector switch	Machine operates as per the status of their respective selector switches	
Select the auto mode by operating its selector switch	The machine operates as per ON / OFF of the output from the PLC of the capsule filling machine	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3.4 FUNCTIONAL VERIFICATION OF SAFETY INTERLOCK CHECKS

Operational Checks	Acceptance Criteria	Observation
AIR DISPLACEMENT UNIT BLOWER MOTOR O/L CHECK		
Select the manual mode by operating the auto / manual selector switch and then switch ON the polishing motor by operating its selector switch	Polishing Machine & Air Displacement Unit blower will start	
Press the test key on the overload relay of Air Displacement Unit blower	Polishing Machine & Air Displacement Unit blower will stop	
Press the reset key on the O/L relay of Air Displacement Unit blower	Air Displacement Unit blower will start (if the manual selector switches are in ON position)	
POLISHING MOTOR VFD CHECK		
Select the manual mode by operating the auto / manual selector switch and then switch ON the polishing motor by operating its selector switch	Polishing Motor will start	
Vary frequency parameter on the VFD of the polishing motor	Polishing Motor will stop	
Press the reset frequency parameter on the VFD of the polishing motor	Polishing Motor will start	

Checked By
Sign & Date:

Verified By
Sign & Date:

Inference:

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Reviewed By
Sign & Date:

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.

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

WHO	:	World Health Organization
cGMP	:	current Good Manufacturing Practices
QA	:	Quality Assurance
OQ	:	Operational Qualification
CPS	:	Capsule polishing machine & Unfilled Capsule Separator
Ltd.	:	Limited
NMT	:	Not More Than
IQ	:	Installation Qualification
mm	:	Millimetre
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
FCS	:	Filled capsule sorter
ID.	:	Identification
mm	:	Millimeter
MCB	:	Miniature circuit break

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			