OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

FILLED CAPSULE SORTER WITH

MINI CAPSULE SORTER

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

CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FILLED CAPSULE SORTER WITH MINI CAPSULE SORTER	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 filled capsule sorter with mini capsule sorter 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, 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 **Filled Capsule Sorter With Mini Capsule Sorter** installed in the Capsule Filling.
- This Protocol will define the methods and documentation used to perform OQ activity the Double Rotary Tablet Compression Machine 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 filled capsule sorter with mini capsule sorter Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Filled Capsule Sorter With Mini Capsule Sorter
Equipment	
Manufacturer's Name	
Model	**MFCS**
Supplier's Name	
Location of Installation	Capsule Filling

6.0 SYSTEM DESCRIPTION:

The entire equipment comprises of the following units:

- **Mini Capsule Sorter Unit**
  - Mini capsule sorter used to sort opened capsule cap or body shells coming from the polishing machine by means of a vibratory system.
  - Mini Capsule Sorter Unit consists of sorting plates having holes with respect to capsule body & cap size.
  - The cap & body separated capsules will then further flow into the filled capsule sorter drum for sorting diametrically distorted capsules.
- **Filled Capsule Sorter Unit**
  - Filled Capsule Sorter Unit consists of sorter drum having holes as per the capsule size
  - The filled capsule sorter unit works on the principle that diametrically damaged or cylindrically out capsules won't pass through the holes on the sorter drum and are collected in the separate bin.
  - The drive to the sorter unit is by directly connected motor & gearbox.
  - A variable frequency drive is provided to vary the RPM of the sorter drum.
  - The electrical controls such as MCB, VFD, etc. are placed in the common SS 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 filled capsule sorter with mini capsule sorter.
- Draft SOP for Preventive Maintenance of filled capsule sorter with mini capsule sorter.
- 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 & cleaning of filled capsule sorter with mini capsule sorter		
4.	Draft SOP for preventive maintenance of Filled Capsule Sorter With Mini Capsule Sorter		

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 Filled Capsule Sorter with Mini Capsule Sorter as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

8.3.1 FCS FUNCTIONALITY TEST:

Operational Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Select the manual mode by operating the auto / manual selector switch and then press the START push button on the operating panel	FCS motor & Vibrator unit will start		
Press the STOP push button on the operating panel	FCS motor & Vibrator unit will stop		

8.3.2 VIBRATOR FUNCTIONALITY TEST

Operational Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Turn the Vibrator selector switch to ON	The vibrator should start		
Feel the vibrations generated when the vibrator controller knob is set at minimum (i.e. 10)	Vibrations generated should be minimum		
Feel the vibrations generated when the vibrator controller knob is set at minimum (i.e. 50)	Vibrations generated should be optimum		
Feel the vibrations generated when the vibrator controller knob is set at maximum (i.e. 100)	Vibrations generated should be maximum.		

8.3.3 AUTO / MANUAL FUNCTIONALITY TEST

Operational Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Select the manual mode by operating its selector switch	Machine operates as per the status of their respective selector switch		
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:

Inference:

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Reviewed By
Sign & Date:

9.0 FUNCTIONAL VERIFICATION OF SAFETY INTERLOCK CHECKS:

Operational Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Select the manual mode by operating the auto / manual selector switch and then switch ON the FCS motor by operating its selector switch	FCS Motor will start		
Vary the frequency parameter on the VFD of the FCS motor	FCS motor will stop		
Press the reset frequency parameter on the VFD of the FCS motor	NA		

10.0 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.

11.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

12.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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13.0 CHANGE CONTROL, IF ANY:

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

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15.0 CONCLUSION:

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16.0 RECOMMENDATION:

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17.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
cGMP	:	current Good Manufacturing Practices
QA	:	Quality Assurance
OQ	:	Operational Qualification
OD	:	Oral Solid Dosage
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

18.0 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:

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