OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

EMPTY CAPSULE SORTER ELEVATOR

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR EMPTY CAPSULE SORTER ELEVATOR	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR EMPTY CAPSULE SORTER ELEVATOR	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 Empty capsule Sorter Elevator 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 **Empty capsule Sorter Elevator (Make- Anchor Mark Pvt. Ltd)** installed in the Capsule Filling.
- This Protocol will define the methods and documentation used to perform OQ activity the Empty capsule Sorter elevator 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 Empty capsule Sorter Elevator Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Empty capsule Sorter Elevator
Equipment	
Manufacturer's Name	
Model	**ECSE**
Supplier's Name	
Location of Installation	Capsule Filling

6.0 SYSTEM DESCRIPTION:

- The Empty Capsule Sorter Elevator is used to sort the empty capsules for any damages and then elevate the good capsule from lower level to the higher level. The Empty Capsule Sorter Elevator is a part of the transfer line for the transfer of empty capsules into the capsule hopper of the Automatic Capsule Filling Machine, which is at higher level.

- The machine works on the principle of vibratory sorting and lifting the capsules by airflow. A linear vibrator vibrates the drilled plate, which sorts the capsules as per the requirement. A continuous stream of air at a high velocity lifts the capsules up as soon as they are fed into the blower inlet chute after sorting them properly. The capsules are fed at a lower level and machine conveys them to a higher level.

- The rotating impeller develops the required airflow for lifting the capsules. The suction of free atmospheric air is through inlet damper and discharged at a higher velocity by the rotating impeller. The sorted empty capsules are fed in the in-feed chute of the machine and are lifted up by the high velocity air stream to the top pipe and then to the delivery chute.

- Control

  The Control system for the equipment is a standard control Auto (PLC+HMI) & Manual based System. Control cum operating panel with all related electrical components is provided at the base of machine.

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 & cleaning of Empty capsule Sorter Elevator		
4.	Draft SOP for preventive maintenance of Empty capsule Sorter Elevator		

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 Empty capsule Sorter Elevator as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

8.3.1 BLOWER FUNCTIONALITY TEST:

Operational Checks	Acceptance Criteria	Observation
Press the Start Push button on the operating panel	The Blower should start	
Press the Stop Push button on the operating panel	The Blower should stop	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3.2 VIBRATOR FUNCTIONALITY TEST

Operational Checks	Acceptance Criteria	Observation
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. 0)	Vibrations generated should be minimum	
Feel the vibrations generated when the vibrator controller knob is set at maximum (i.e. 100)	Vibrations generated should be maximum.	
Turn the Vibrator selector switch to OFF	The vibrator should stop	

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
FDA	:	Food and Drug Administration
cGMP	:	current Good Manufacturing Practices
QA	:	Quality Assurance
OQ	:	Operational Qualification
ECS	:	Empty Capsule Sorter Elevator
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)			