INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

EMPTY CAPSULE SORTER

ELEVATOR

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

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

CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of **Empty Capsule Sorter Elevator**.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification **Empty Capsule Sorter Elevator (Make – Anchor mark)** to be installed in the Capsule filling.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Automatic Capsule Filling 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	• Initiation, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Qualification activity. • Monitoring of Installation 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 Machine Installation 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 BRIEF PROCESS 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:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction 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 IQ 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 GENERAL CHECKS AND LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation
Grouting And Mounting	Should be grouted & mounted properly.	
Leveling	The equipment should be balanced and leveled properly.	
Edges of parts	All the edges of metal parts should be grinded and no sharp edges should be there.	
Welding of Joints	The welding joints should not have any burrs.	
Place of Installation	Capsule filling-01	
Illumination in area	NLT 300 Lux.	
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.2 PRELIMINARY CHECK LIST – OVERALL CONDITION:

S.No.	Checks to be performed:	Observation
1.	Check for the overall dimensions	
2.	Check for the receipt of the consignment with reference to the packing list	
3.	Check for the horizontal leveling and proper positioning of the equipment	
4.	Check for scratches on the machine body	
5.	Check for the condition of the electrical components in the control panel and their wiring	

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Sign & Date:

Verified By
Sign & Date:

8.3 COMPONENT LOCATION LIST:

S.No.	Component	Location	Observation
1.	**Blower Motor**	Base cabinet	
2.	**Blower**	Attached to the motor	
3.	**Capsule hopper**	Top of the machine	
4.	**Hopper lid**	On the hopper	
5.	**Sorting tray**	Front end of the machine	
6.	**Transfer pipe**	Front end of the machine - after the sorting tray	
7.	**ON / OFF switch**	Base cabinet - Outer end	
8.	**Start green IPB push button**	Base cabinet - Outer end	
9.	**Stop red push button**	Base cabinet - Outer end	
10.	**Selector switch**	Base cabinet - Outer end	
11.	**Control ON indicating lamp**	Base cabinet - Outer end	
12.	**MCB**	Control Panel – within the base cabinet	
13.	**Contactor**	Control Panel	
14.	**Vibrator**	Control Panel	
15.	**Over load relay**	Control Panel	

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Sign & Date:

Verified By
Sign & Date:

8.4 DETAILED COMPONENT CHECK LIST – PHYSICAL SPECIFICATION:

S.No.	Component Description	Specification	Observation
Mechanical			
1.	**Blower**	Make – Minivac SVR 70N, 2810 RPM, 415 V, 50 HZ	
Electrical			
1.	**Blower Motor**	Make – Hindustan Motors , 0.5 HP, 2810RPM, 415 V, 50 HZ	
2.	**ON / OFF switch**	Make – Salzer, 16 A	
3.	**MCB for Blower Motor**	Make – Schneider Electric, 6A, 3 poles	
4.	**MCB for control circuit**	Make – Schneider Electric, 2A, 1 pole	
5.	**Contactor for Blower Motor**	Make – Siemens, Model–3TF30 10E	
6.	**Over load relay for Blower Motor**	Make – Siemens, 3UA50, Range – 0.8 – 1.25 A	
7.	**Start green IPB push button**	Make – Teknic, code: 2LHB4	
8.	**Stop red push button**	Make – Teknic, code: 2AP4	
9.	**Selector switch**	Make – Teknic, Two way	
10.	**Control ON indicating lamp**	Make – Teknic 230V AC	
11.	**Vibrator Controller**	Make – Good Earth 230VDC	

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Verified By
Sign & Date:

8.5 VERIFICATION OF TEST CERTIFICATES:

S.No.	Component	Type of Certificate	Observation
1.	Blower	Test Certificate	
2.	Blower motor	Test Certificate	

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Sign & Date:

Verified By
Sign & Date:

8.6 POWER AND UTILITY CHECKLIST:

S.No.	Utility Parameter	Method of verification	Acceptance Criteria	Observation
1.	**Phase**	Visual Check	3 Phase	
2.	**Voltage**			
3.	**Test** **(Using Multimeter)**	R ⏚ N Y ⏚ N B ⏚ N	415 V ± 10% 415 V ± 10% 415 V ± 10%	
4.	**Frequency**	Multimeter	50 Hz ± 5%	

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
UCS	:	Empty/Unfilled Capsule Sorter
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
OD	:	Oral Solid Dosage
FCS	:	Filled Capsule Sorter
SS	:	Stainless Steel
MOC	:	Material of Construction
mm	:	Millimeter
AC	:	Alternating Current
HP	:	Horse Power
V	:	Volt
Hz	:	Hertz
NMT	:	Not More Than
RH	:	Relative Humidity
QA	:	Quality Assurance
IQ	:	Installation Qualification
No.	:	Number
MOC	:	Material of construction
NLT	:	Not less than

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			