DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR EMPTY CAPSULE SORTER ELEVATOR

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

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PHARMA DEVILS	DESIGN 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 MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, GMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Empty Capsule Sorter Elevator with GMP Model.
- The equipment shall operate under the dust free environment and conditions as per the GMP requirements.
- The drawings and P & ID’s provided by Vendor shall be verified during Design Qualification.

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 and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration. ➢ Material of construction of Product Contact Parts. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol after Execution.

5.0 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification. This is Automatic capsule filling machine.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Parameters	Acceptance Criteria	Reference
Model	The equipment should be a GMP compliant model.	Design Requirement
Material of Construction	All contact part should be made up of SS 316L. Other non-contact component are of Aluminum	Design Requirement
Cleaning & Maintenance	Should be easily cleanable and maintainable	Design Requirement
Control System	Equipment to be controlled.	Design Requirement
Electrical System	The electrical system of the equipment to be housed as per the GMP & GEP slandered	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	3 Phase Plus Earthing, 5 Wire Line Up To The Panel Board Terminal. Voltage.: 415 V Frequency.: 50 Hz (To be assured by Engineering Department)	GMP Requirement
Electrical Connections on Machine/Panel	415V, 3 Phase, 50 Hz,	
Room Condition	Should be able to meet the requirement of clean environment.	

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S. No.	Parameter	Specification
1.	**Capacity / Output**	Compatible to A-120
2.	**Capsule size**	Machine is suitable for Any size from '00' to '4, however Size#0, and Size#3 are supplied, as ordered.
3.	**Sorter assembly**	A vibrator is used for generating the vibration required for the sorting of the capsules. The vibrator controller can vary the vibrations of the vibrator. The chute from the vibrator assembly guides the capsules towards the blower inlet
4.	**Surface Finish**	Internal Product Contact Parts - Mirror Finish
		External Zone - Matt Finish

5.	**Mode of machine cleaning**	Manually
6.	**Room temperature**	NLT 20 deg C and NMT 25 deg C
7.	**Room humidity**	NLT 45 %RH and NMT 55 %RH
8.	**Blower**	CFM 70, 2800 RPM, vacuum 50
9.	**Blower motor**	0.5 HP

7.4 MATERIAL OF CONSTRUCTION:

S. No.	Parts Name	Material of Construction
1.	**Capsule Hopper**	SS 316
2.	**Sorting Tray Holder**	SS 316
3.	**Sorting Plate**	Aluminium
4.	**Chute Elevator Pipe**	SS 316
5.	**Elevator Seamless Pipe**	SS 316
6.	**Discharge Nozzle with Cover**	SS 316
7.	**Elevator Pipe elbow**	SS 316
8.	**Capsule hopper**	SS 316
9.	**Elevator Seamless Pipe**	SS 316
10.	**Chute**	SS 316

7.5 PRODUCT SURFACE CONTACT AREAS:

S.No.	Component	Surface Area (in sq. mm)
1.	**Capsule Hopper**	1459422.31
2.	**Sorting Tray Holder**	227873.97
3.	**Sorting Plate**	59904.97
4.	**Chute Elevator Pipe**	82581.46
5.	**Elevator Seamless Pipe**	260009.32
6.	**Discharge Nozzle with Cover**	201841.02
7.	**Elevator Pipe elbow**	28655.70

7.6 MAJOR BOF COMPONENT DETAIL:

S.No.	PARTICULARS	SPECIFICATIONS
1.	**Blower Motor**	Hindustan Motors / Equivalent
2.	**Blower**	Minivac blower / Equivalent
3.	**Main ON / OFF switch**	L & T Salzer / equivalent
4.	**Push buttons (Blower ON/OFF)**	Teknic / Equivalent
5.	**Selector switch (Vibrator ON/OFF, Auto/Manual)**	Teknic / equivalent
6.	**Vibrator & Vibrator controller**	Good Earth / equivalent
7.	**Terminals**	Connectwell / equivalent

7.7 LIMITING CONDITION FOR MACHINE PERFORMANCE:

- **Power Failure**

In the event of power failure, the process shall halt and shall start only on restoration of power.

- **Control Panel Failure**

Failure in the control panel shall result in the stoppage of process. The process will start only on rectifying by operator intervention.

7.8 POWER AND UTILITY CONSUMPTION:

S.No.	PARTICULARS	SPECIFICATIONS
Power Consumption		
1.	Voltage	415 V $\pm$ 10%
2.	Frequency	50 Hz $\pm$ 5%
3.	Connected Load	0.37 kW

7.9 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selections of Vendor for supplying the Empty Capsule Sorter Elevator Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review is include vendor background (general/ financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as specified in PO.

(2) Operating and service manual for Automatic Empty Capsule Sorter Elevator Machine.

Reviewed By
Sign & Date:

8.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

PVT.	:	Private limited
LTD.	:	Limited
DQ.	:	Design Qualification
FCS	:	Filled Capsule Sorter
UCS	:	Empty Capsule Sorter Elevator
BOF.	:	Brought out of items
URS.	:	User Requirement Specification
MCB	:	Miniature Circuit Breaker
MOC	:	Material of Construction
%	:	Percentage
GMP	:	Good Manufacturing Practice
Hz	:	Hertz
H.P.	:	Horse Power
A.C.	:	Alternating Current
V	:	Voltage
mm	:	Millimeter
S.S.	:	Stainless Steel
GA	:	General Arrangement
M. S.	:	Mild Steel
NLT	:	Not Less then
NMT	:	Not More then

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			