DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

COATING PAN 36”

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

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”

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1.0 PROTOCOL PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”

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, cGMP 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 of **Coating Pan (Make:** Sehgal Engineers**) (Pan Diameter:** 36 Inch**, Capacity:** 80 Kg**)** to be installed.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

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	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design 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. • Review of Design 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. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Design Qualification Protocol cum Report after Execution.

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5.0 BRIEF PROCESS DESCRIPTION:

The Coating Machine consists of a M.S. Base housing with motor holding a 36 inch elliptical shaped stainless steel pan which rotates about an axis inclined 45 degrees to the horizontal. The shaft holding the Coating Pan is connected with a gear box which is connected to a motor of 3 HP and 3 phase with the help of a V belt. The motor is connected to a reverse switch and a starter. The starter green push button is used to start the pan rotating while the red button is used to stop the pan rotating. The direction of the reverse switch should be change to change the direction of the pan rotation.

The Pan is serviced with a controlled air blast with variable temperature control (the control panel is equipped with 3 temperature control position whereby one, two or three heaters are in operation providing air of variable temperature). A standard type of fan blower is provided to supply the necessary air blast to the pan. The drop pipe from the blower is about 6 inch in diameter. The exhaust system must provide the lift of the suction greater than that of the pressure of the hot air in the hot air pipe. The exhaust air system is built separately in house.

Properly de-dusted tablet cores are fed into the coating pan, press the green starter button the pan rotating and allow the tablets to tumble in the pan. With the correct pan load, three dimensional circulations is established and sufficient volume of coating solution is applied by a spray system whereby atomization is achieved by the pneumatic system operation at a pressure of 01 and 150 psi. A stream of hot air is directed onto the tablet bed to aid the drying process. The temperature and amount of air is controlled so that the solution has an opportunity to spread uniformly on the tablets before drying. When the tablets are no longer tacky and the cost is dried sufficiently, the drying air is shut off and further coating solution is applied (subsequent application require less coating solution because the tablets are no longer porous). Hand manipulation of the wetted tablets ensures that the solution is evenly distributed and a satisfactory tumbling action is maintained while the coating is dried by a stream of warm air.

Additional application of the coating solution is made at intervals of approximately 10 minutes and then dried with warm air until the desired thickness is obtained. The last two coats should be applied without drying air so that the coating material will dry slowly, resulting in a smooth glossy surface.

The system consists of:

1. Basic Body
2. Coating Pan
3. Blower
4. Heater
5. Gear Box

6. Blower Pipe
7. Fan
8. Control Panel

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS / PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Coating Pan Machine should be able to coat the core tablets.	Coating Pan Machine should meet the requirement for coating the core tablets.	Process Requirement
Working: Working of Coating Pan machine	Coating Pan Machine should capable of coating the core tablets with desired set parameters as per requirement.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed is service area.	cGMP Requirement
Room Condition	Temperature and RH requirement as per requirement of product.	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Coating Pan	SS 316, elliptical shaped non perforated 36 inch pan with a circular mouth for charging & discharging of tablets, mounted at an inclination of 45 degrees to the horizontal.	Design Requirement
Spray Gun	Highly sophisticated and efficient 1 No. spray gun. The gun is mounted on SS retractable header with angle adjustable arrangement. The retractable header can rotate up to 90º for easy cleaning/washing. Spray pattern (angle) can be controlled manually.	Design Requirement
Coating Application System	It contains 1 No., 1 liter solution holding vessel (SS 316) connected with the spray gun.	Design Requirement
Drive Assembly	Consists of a suitable 1HP, 3 Phase, 440 V and 1440 RPM TEFC motor with suitable worm reduction gearbox and cone pulley arrangement to give three-speed output.	Design Requirement
Dust Collector	Exhaust air is passed through dry scrubbing system, comprises MS scrubber with inlet and outlet connections, fed through series of cartridge filter.	Design Requirement
Hot Air Blower	Hot air blower consisting of suitable 0.5 HP, 3 Phase, 440 V, 2880 RPM TEFC electric motor & centrifugal blower with damper delivering required CFM. The air is heated by means of suitable electric heater to give air at 30 to 90 degrees heater with thermostat control and flexible hose pipe.	Design Requirement
Controls	Unit provided with suitable control panel with starters and push button to actuate the drive and for blower The circuits consists of MCB, relay and contractor in series Ample overload protection is provided by the MCB and the relay wires coming out of the connections are numbered for easy recognition.	Design Requirement

Critical Variables	Acceptance Criteria	Reference
Mounting	The motor and gearbox is mounted inside sturdy MS frame and the pan mounted on the Gearing housing fitted in the stand. Blower mounted by the side of the stand or placed in remote location if required.	Design Requirement
Finish	All joints Argon Arc welded and all SS Parts polished to suitable finished required for smooth finish.	Design Requirement
RPM of Pan (Empty)	12-35 RPM	Design Requirement
Pressure Gauge	Make : TECHNO Range : 0 - 10 kg/cm^2 or 0 - 150 psi.	Design Requirement
Pneumatic FRL Unit	Make : TECHNO Quantity : 02 Nos. Model : AW4000-04, AL4000-04, Pressure : 0.15 - 0.85 Mpa	Design Requirement
Temperature Controller	Make : SELEC Type : TC 303	Design Requirement
MCB	Make : L & T Model : BB3032OC Type : C32-240/415 V	Design Requirement
Loading Capacity	60-80 Kg	Design Requirement

7.4 MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Reference
Coating Pan	SS 316	Design Requirement
Solution Holding Vessel	SS 316	Design Requirement
Guns Nozzle, Cap, Needle	SS 316/SS 304	Design Requirement
Operating Panel	SS 304	Design Requirement
Power Panel	MS Powder Coated	Design Requirement
Tubing’s	Silicon	Design Requirement
Spraying Arm	Silicon	Design Requirement
Blower Impeller	MS	Design Requirement

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	Safety Requirement

7.6 VENDOR SELECTION:

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

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:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
db	:	Decibel
V	:	Volt
MS	:	Mild Steel
Psi	:	Per Square Inch
HP	:	Horse Power
RPM	:	Revolution per Minute
TEFC	:	Totally Enclosed Fan-Cooled
CFM	:	Cubic Feet per Minute
FRL	:	Air Filter Regulator Lubricator
No.	:	Number
RH	:	Relative Humidity

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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HEAD (QUALITY ASSURANCE)			