



**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTO COATER - 37"**

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR AUTO COATER - 37"

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1.0 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)			



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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 **Auto Coater (Make: Solace Engineers Pvt. Ltd., 37")** .
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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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	<ul style="list-style-type: none">• Initiation, Approval and Authorization 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.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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.<ul style="list-style-type: none">➤ 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• Post Approval of Qualification Protocol after Execution.



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5.0 BRIEF EQUIPMENT DESCRIPTION:

Auto Coater is an automated tablet coating system particularly perform coating over uncoated tablets with different sizes greater than 3 mm, complete operations is carried out in closed system with cGMP compliance.

The main pan unit consists of a cylindrical perforated pan with conical ends in a SS double – walled enclosure. Coating fluid is sprayed through multiple air borne spray gun mounted with in the pan. A peristaltic pump is employed for accurate delivery of coating fluids. The tablet bed is smoothly and efficiently mixed during pan rotation with the aid of mixing baffles attached internally with in the pan. The coated tablet cores are dried with heated, dehumidified air supplied from an inlet AHU – which contains a dehumidification and heating system as well as sequential battery of 10 μ , 3 μ and 0.3 μ . During this process applied coating is dried with non- contaminated, dust free environment and optimized volume of air, for producing uniformly coated tablet cores.

The system consists of:

1. Main unit with inbuilt automatic washing facility.
2. Air handling Unit. (AHU)
3. Spraying system
4. Wet Scrubber System
5. Solution holding system with an agitator assembly
6. Automation and control system

6.0 EQUIPMENT SPECIFICATION:

Equipment Specification document is provided to manufacturer for engineering equipment in the user requirement specification (URS).



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Auto Coater should be able to coat the core tablets.	Auto Coater machine should meet the requirement for coating the core tablets	Process Requirement
Working: Working of Auto Coater	Auto Coater should capable of coating the various tablets with desired set parameters as per requirement	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	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	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 in service area.	cGMP Requirement
Room Condition	Temperature and RH requirement as per requirement of product	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Cylindrical Pan	AISI 316, perforated 37"/ 940 (±10 mm) with 3 mm holes	Design Requirement
Baffles	AISI 316, Reverse scoop type alternately placed to ensure proper mixing and avoid any dead areas. Total 6 nos. of baffles are placed within the pan.	Design Requirement
Spray Gun	Highly sophisticated and efficient 3Nos. spray gun free from choking problems, controls both the application rate and the droplet size for all type of coating. The guns are mounted on SS retractable header with angle adjustable arrangement, depending on the shape, size and pattern of rolling of tablets. After withdrawing/operation, the retractable header can rotate up to 90° for easy cleaning/washing. All SS, four point spray gun, Spray pattern (angle) can be controlled from the control panel while operation.	Design Requirement
Sensor	To sense measure and transducer temperature and regulatory indication and interlock function	Design Requirement
Sink	To Collects wash water/solution during washing and enables rotating perforated pan/drum to run through collected wash water in sink. The later is provided with pipe with valve assembly, for draining water after wash cycle.	Design Requirement
Coating Application System	It contains 1 Nos. 75 liter, solution holding vessel (AISI 316 L) with a top entry. Centrally located agitator driven by air motor. The system contains guns with film coating header, peristaltic pump and necessary tubings.	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Peristaltic Pump	Peristaltic pump for precise and rapid priming facility for proper and accurate dosing of solution, supply shall be complete with solution transfer tube with four numbers individual cassette (pump head), shall be provided for each spray gun to obtain uniform spray from individual spray gun while coating	Design Requirement
Air Handling System	All air handling system will be modularly constructed to allow quick and easy remove of sub-assembly for maintenance and repair.	Design Requirement
Hot Air Delivery	<p>a) Integrated unit includes sequential filtration of fresh air through filters of 10 μ. Pre-clarified air is drawn through steam heater prior to inlet blower. Heated air is conveyed through the discrete filter cabinet containing 5μ and 0.3μ HEPA filters respectively. Pre filter should be non-woven synthetic media, which is cleanable with air only.</p> <p>b) <u>Centrifugal fan</u>: driven by 2 HP/AC Motor. Capacity 1300 CFM ($\pm 5\%$) Hot air is introduced through top of the pan enclosure.</p> <p>c) <u>Heating chamber</u>: Coil with Copper tube with aluminium fins, Steam inlet connection and condensate outlet for raising temperature and to control the temperature from ambient (30°C to 85 °C). Flow of saturated steam @ 2-4 BAR is regulated by Steam Valve as per preset inlet temperature.</p> <p>d) Finally hot and dehumidified air should be passed through 0.3 μ HEPA filters mounted in sealed enclosure.</p>	Design Requirement
Exhaust Fan	a) Exhaust fan driven by 5 HP Motor/AC, evacuates the drying air from the pan.	Design Requirement
Final Filtration System	5 μ Micro filter and 0.3 μ HEPA filter encased in single skin GI powder coated box.	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Mounting	PAO testing port after HEPA filter should be provided for testing the integrity of HEPA filter.	Design Requirement
Dry Scrubber	Exhaust air pass through dry scrubbing system, for minimizing expulsion of dust & coating resins from coating system, comprises MS dust collector with inlet & outlet connection, fed through series of cartridge filters.	Design Requirement
Controls	Total coatings operations are to be controlled PLC/H.M.I. Operation and control shall be accessible from panel operators console, interface and off – site printer.	Design Requirement



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7.3.1 TECHNICAL SPECIFICATIONS OF COMPONENTS AND SUB-COMPONENTS USED:

S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
1.	Drive Section	Gear box	Design Requirement
		Make: Elecon Engineering	
		Type: SNU 4"	
		Motor for pan: 2 HP, 1420 RPM,	
		Make: Crompton Greaves	
		Rating: 2 HP/415 V, 3 HP, 1420 RPM	
		Type: Flame proof	
2.	Timing Belt and Pulley	Belt: 1 No.	Design Requirement
		Make: Contitech	
		Model: 600H	
		Pulley: 2 nos.	
		Motor: 3" Dia	
		Gear box side: 6" Dia.	
3.	Pillow Bearing	Model: UCF 314	Design Requirement
4.	Air Handling System	Make: Ethos	Design Requirement
		Design Qualification	
		Type of unit: Double Skin Type	
		Capacity: 1300 CFM	
		Installation Qualification	
		Make: Centrifugal, backward curved type BDB- 225	
		Motor: 1 No.	
		Make: ABB- TEFC foot mounted 1.5 HP/2 Pole/2830 RPM	
		Cooling coil:	
		Tube: ½" OD Copper 12 Rows	
		Fins: 0.13 thk x 12-13 Alu/inch	
		Steam Coil	
		Tube: ½" OD Copper 8 Rows	



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
		Fins: 0.13 thk x 12-13 Alu/inch Coil Header Size & Material : 3/4" Socket (BSP) 10 μ Pre-filter: 01 No. Type: Flanged type pleated Size: 610 mm x 610 mm x 50 mm Efficiency: 90% down to 10 μ 5 μ Fine-filter: 01 No. Type: Flange Type Size: 610 mm x 610 mm x 300 mm Efficiency: 95% down to 5 μ 0.3 μ Pre-filter: 01 No. Type: Flange Type HEPA Size: 610 mm x 610 mm x 300 mm Efficiency: 99.99% down to 0.3 μ	
5.	Wash In Place	Wip Nozzles: 01 No. Make: Solace Engineers. Type: flood jet 1.5 mm Spray rate: 50 LPM MOC: AISI 304 Wash: Raw Water, Potable Water, DM Water Type: Flame proof	Design Requirement
6.	FLP	FLP Light: 01 No. Make: Prompt	Design Requirement
7.	Solution Tank with Agitator	Make: Solace Engineers Pvt. Ltd. Capacity: 75 Liter MOC: AISI 316 L (Contact parts) AISI 304 L (Non Contact parts) Quantity: 01 No.	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
		Agitator Air Motor Make: Tonson (Taiwan)	
8.	Peristaltic Pump	Make: Thermofisher Scientific –USA Model: E-67909, 24 VDC	Design Requirement
	Peristaltic Pump Head	Model: 1900-1949,24V Make: Masterflex L/S No. of Head: 03 Nos. (Detachable)	Design Requirement
9.	Exhaust Blower with Motor	Make: RIB Engineers Motor: 5 HP, 415 V, 50 HZ AC	Design Requirement
		Make: Crompton Greaves/Hindustan	
10.	Spray Guns	Make: Spraying System Co (USA) Model: 1A-40-1/8 VAU316LSS Qty.: 03 Nos.	Design Requirement
11.	Dampers	Make: Solace Engrs (Mktg) Pvt. Ltd. Actuator: Rotex (India) or Reputed	Design Requirement



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7.3.2 PROCESS CONTROL INSTRUMENTS/MEASURING DEVICE FOR DESIGN REQUIREMENT:

S. No.	COMPONENT	SPECIFICATION	REFERENCE
1.	Display (MMI)	1 Nos	Design Requirement
	Make	Mitsubishi	
	Model	10.4 " CTS	
2.	Programmable Logic Controller	1 No.	Design Requirement
	Make	Mitsubishi	
	Model	FX3U-32MR/ES	
3.	Analog Module - RTD	1Nos.	Design Requirement
	Make	Mitsubishi	
	Model	FX3U-4ADPT-ADP	
4.	Analog Input & Output module	1 No.	Design Requirement
	Make	Mitsubishi	
	Model	FX3U-3A-ADP	
5.	Residual Current Circuit Breaker	1 No.	Design Requirement
	Make	C & S	
	Capacity	63 Amp, 4 Pole	
6.	Miniature circuit breaker	1 Nos.	Design Requirement
	Make	Siemens	
	Capacity	40 Amp,100 mA 4Pole	
7.	Miniature Circuit Breaker	2 Nos.	Design Requirement
	Make	Siemens	
	Capacity	4 Amp,	
	Pole	3 Pole	



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S. No.	COMPONENT	SPECIFICATION	REFERENCE
8.	Miniature Circuit Breaker	1 Nos.	Design Requirement
	Make	Siemens	
	Capacity	10 Amp, 3Pole	
9.	Power Supply	1 No.	Design Requirement
	Make	Siemens	
	Capacity	5 A	
10.	Bimetal Overload	1 Nos.	Design Requirement
	Make	Siemens	
	Model	3.2 - 5 Amp	
11.	Relay Card	2 Nos.	Design Requirement
	Make	Reputed	
	Channel	8	
12.	Air Pressure Switch	2 Nos.	Design Requirement
	Make	Danfoss	
13.	Air Pressure Regulator	3 Nos.	Design Requirement
		. Janatics	
		3/8" BSP –	
14.	Solenoid Valve (5/2 Way)	2 Nos.	Design Requirement
	Model	5/2 way	
	Make	Janatics	
15.	Solenoid Valve (3/2 Way)	2 Nos.	Design Requirement
	Model	3/2 way	
	Make	Janatics	
16.	Steam Control Valve	1 No.	Design Requirement
	Size	25 mm S/E 2/2 way Pneumatically operated ON-OFF control valve (Flanges Provided)	



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S. No.	COMPONENT	SPECIFICATION	REFERENCE
17.	Steam Condensate Valve	1 No.	Design Requirement
	Size	15 mm S/E 2/2 way Pneumatically operated ON-OFF control valve (Flanges Provided)	
18.	Chilled Water Valve	1 No.	Design Requirement
	Make	Aira	
	Size	25 mm, 3 way double acting pneumatic actuator operated F/E Valve	
19.	Pan Motor VFD	1 No.	Design Requirement
	Make	Siemens	
	Capacity	2 HP	
	Model	FR-D740-036-EC	
20.	Inlet Motor VFD	1 No.	Design Requirement
	Make	Mitsubishi	
	Capacity	2 HP	
	Model	FR-D740-036-EC	
21.	Exhaust Motor VFD	1 No.	Design Requirement
	Make	Mitsubishi	
	Capacity	5 HP	
	Model	FR-D740-080-EC	
	Bed Temperature Sensor	1 No.	Design Requirement
	Make	Sensewell	
23.	ON-OFF Switch	1 No.	Design Requirement
	Make	Teknic/Equivalent	



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S. No.	COMPONENT	SPECIFICATION	REFERENCE
24.	Emergency Stop Push Button	1 No.	Design Requirement
	Make	Teknic/Equipment	
25.	Alarm Indicator (Buzzer)	1 No.	Design Requirement
	Make	Mimic	
26.	Pressure Gauge	2 Nos.	Design Requirement
	Make	Arbuda	
	Range	0-10.6 kg/cm ²	
27.	R.H Sensor	1 No.	Design Requirement
	Make	Novus	
	Model	RHT-DM	
	Output	4-20 mA for 0-100% RH	
	Power Supply	12-30 VDC 2 wire	
	Range	0-100% RH	
	Repeatability	±1% RH	
28.	Peristaltic Pump Controller	1 No.	Design Requirement
	Make	Reputed	
29.	Silicone Gasket	1 Set	Design Requirement
	Make	M. K. Silicone	
30.	Silicone Transil Tubing	1 Set	Design Requirement
	Make	Ami Polymer	
	Size	OD 8 mm x ID 5 mm	
31.	Inlet & Outlet Sensor	2 Nos.	Design Requirement
	Make	Sensewell	
	Model	RTD PT-100	
	Dimensions	Dia 6 mm x 150 mm Long FLP Head ¼ BSP Adjustable	



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S. No.	COMPONENT	SPECIFICATION	REFERENCE
32.	Scrubber Pump	1 No./2 HP	Design Requirement
	Make	Lubi	
	Model	LCR 4/7	
	Head	56 Mtr.	
33.	Solid State Relay	1 No.	Design Requirement
	Make	Unison	
	Capacity	25A	
34.	Washing Valve	1 No.	Design Requirement
	Make	Aira	
35	Contractor	1Nos	Design Requirement
	Make	Siemens	
36	LED	1Nos	Design Requirement
	Make	Siemens	
	Red	3SB2585-6HF03	
	Yellow	3SB2585-6HF03	
	Blue	3SB2585-6HF03	
37	Service Socket	1 Nos	Design Requirement
	Make	Anchor	
38	Panel Mounting FAN	1Nos	Design Requirement
	Model	4"	
39	SS304 Air Manifold	1Nos	Design Requirement
	Make	Solace	



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7.4 MATERIAL OF CONSTRUCTION:

Name of components	Material of construction	Reference
1. Contact parts		
Perforated Pan	AISI 316L	cGMP Requirement
Mouth Ring	AISI 316L	
Mouth Box	AISI 316L	
2. Non contact parts		
Machine Body	AISI 304	Design Requirement
Side & Back Doors	AISI 304	
Damper	AISI 304	
WIP Piping	AISI 304	
Operating Panel	AISI 304	
Base of Machine	AISI 304	
Power Panel	MS	
Ductings Interconnecting	AISI 304	
Blower Impeller	MS Painted	



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7.5 SAFETY:

I) Interlock (Process Event)	Reference
Inlet air blower trip	Design Requirement
Exhaust air blower trip	Design Requirement
Pan motor trip	Design Requirement
Pan motor jam	Design Requirement
II) Alarms/Message	
Dosing stop as bed temperature high	Design Requirement
Dosing stop as bed temperature low	Design Requirement
Incoming air pressure low	Design Requirement
Atomization air pressure low	Design Requirement
Inlet temperature low	Design Requirement
Inlet temperature high	Design Requirement
Outlet temperature low	Design Requirement
Outlet temperature high	Design Requirement
Tablet bed temperature low	Design Requirement
Tablet bed temperature high	Design Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Auto Coater Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review 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) Specifications and Requirements as specified in P.O. and URS.
(2) Operating and service manual for Auto Coater Machine.



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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- 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
QA	:	Quality Assurance
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
C.I	:	Cast Iron
RH	:	Relative Humidity
PLC	:	Programmable Logic Controller
VFD	:	Variable Frequency Drive
HP	:	Horse Power
Kw	:	Kilo Watt
HP	:	Horse Power
V	:	Volt
Hz	:	Hertz
RPM	:	Revolution per minute
WIP	:	Washing in Place
LPM	:	Liter per Minute



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			