INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

AUTO COATER – 37’’

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTO COATER - 37”

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTO COATER - 37”

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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTO COATER - 37”

2.0 OBJECTIVE:

- To provide documented evidences for the Installation Qualification of Auto Coater to be installed in the Coating.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design, P & ID and Vendor’s recommendations.

3.0 SCOPE:

- The scope of this Installation Qualification Protocol cum Report is limited to the qualification of **Auto Coater (Make – Solace Engineers Pvt. Ltd. 37”)** to be installed in the Coating.
- This document provides all the relevant information’s related to specifications, Installation checks and acceptance criteria to be required for installation qualification activity.

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, Compilation and Authorization of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in a Auto coater Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution

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5.0 EQUIPMENT DETAILS:

Equipment Name	Auto Coater 37’’
Equipment ID.	
Manufacturer’s Name	Solace Engineers Pvt. Ltd.
Serial no.	
Model	cGMP Model
Supplier’s Name	Solace Engineers Pvt. Ltd.
Location of Installation	Coating

6.0 SYSTEM DESCRIPTION:

Auto coater is an automated tablet coating system for efficient film coating of tablets with cGMP compliance in closed condition. The main pan unit consists of a cylindrical perforated pan with conical ends in a SS double walled enclosure. Tablet to be coated are charged into the pan. During the coating process, coating fluids are sprayed through multiple. Air borne spray Gun (s) mounted with in the pan. A peristaltic pump is employed for precise delivery of coating fluids. The tablet bed is gently and efficiently mixed during pan rotation with the aid of mixing baffles attached internally, with in pan. The coating tablet cores are dried with heated dehumidified air supplied form an inlet AHU – which contains a dehumidification and a heating system as well as sequential battery of 10µ, 5µ, 0.3µ filters. As a result, applied coating is dried with non- contaminated, dust free and optimized volume of air, for producing uniformity 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

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document of Auto Coater.
- Piping and Instrumentation Diagram (P& ID).
- Electrical Circuits Diagram.
- 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.
- 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.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be grouted and mounted properly.		
Leveling	Should be properly balanced and leveled		
Edges of Parts	Metal edges should be properly Grounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Coating		
Room Condition	Temp and RH should be 23 ± 2 °C, 50 ± 5 %		
Illumination in Area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Machine Inspection	Ensure that all parts are present and not damaged.		
Electrical component verification	Ensure that the electrical components match to the descriptions in D.Q		
Dimensional verification	Ensure that Auto coater physically fit to location. And properly match with Inlet-exhaust blowers, inter-connecting Air ducts, panel, scrubber etc		

Checked By
(Production)
Sign/Date: ……

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(Manager QA)
Sign/Date: ……

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8.2 Installation Checks:

8.2.1 Key Design Features:

S. No.	Specification	Observation	Observed By (Engineering) Sign/Date	Verified By (QA Officer) Sign/Date
1.	Check the proper mechanical installation of Auto Coater Machine			
2.	Check the proper electrical installation of Auto Coater Machine			
3.	Check the parts are working properly			
4.	Check the equipment is free from any defects			
5.	Check the finishing of product contact parts			

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8.3 Utilities Provided:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Utility connections should be available as per the manufacturer’s specification.			
Electrical Supply	3 Phase Voltage - 415 ± 10% Frequency -50 Hz ± 5%		
Compress Air Supply			
Pressure	6 Bar (kg/cm^2)		
Flow Rate	20 – 25 CFM		
Steam Supply			
Pressure	2 - 4 Bar		
Flow rate	30-40 kgs/Hr		
Chilled Water Supply			
Temperature	6 - 8 ºC		
Quantity	19000 LPH		

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8.4 MOC Verification List:

S.No.	Component	MOC	Observation	Observed by (Engineering) Sign/Date
Contact Parts				
1.	**Perforated Pan**	AISI 316L		
2.	**Mouth Ring**	AISI 316L		
3.	**Mouth box Cone**	AISI 316L		
Non Contact Parts				
4.	**Machine Body**	AISI 304		
5.	**Side & back Doors**	AISI 304		
6.	**Damper**	AISI 304		
7.	**WIP Piping**	AISI 304		
8.	**Operating Panel**	AISI 304		
9.	**Base of Machine**	AISI 304		
10.	**Power panel**	MS		
11.	**Ducting Interconnecting**	AISI 304		
12.	**Blower impeller**	MS Printed		

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8.5 Drawing Verification:

Reference Engineering Drawings	Available (Yes/No)	Observed By (Engineering) Sign/Date
General Arrangement Diagram		
Power Circuit Diagram		
Pneumatic Connections Diagram		
Pneumatic Diagram for Solenoid valve		
Panel Physical Layout		
Circuit Diagram for PLC Controls		

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8.6 Equipment Verification:

8.6.1 Technical Specifications:

S.No.	Description	Observation	Observed By (Engineering) Sign/Date	Verified By QA Sign/Date
1.0	**Drive Section:**			
	Gear Box			
	Make: Elecon Engineering			
	Type: SNU 4”			
	Motor for pan: 2 HP, 1420 RPM			
	Ref No.:NFAM11281			
	Make: Crompton Greaves			
	Rating: 2 HP/415 V, 3 HP, 1420 RPM			
2.0	**Timing Belt and Pulley:**			
	Belt: 1 No.			
	Make: Contitech			
	Model: 600H			
	Pulley: 2 Nos.			
	Motor: 3” Dia			
	Gear box side: 6”Dia.			
3.0	**Pillow Bearing:**			
	Model: UCF 314			
4.0	**Air Handling Unit**			
	Make: Ethos			
	Design Qualification			
	Type of Unit: Double skin type			
	Model : 1300 CFM			
	Installation Qualification			
	Make: Centrifugal,			

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S.No.	Description	Observation	Observed By (Engineering) Sign/Date	Verified By QA Sign/Date
5.0	backward curved type BDB- 225			
	Motor: 1 No.			
	Make: ABB- TEFC foot mounted 1.5 HP/2 Pole/2830 RPM			
6.0	**Cooling Coil**			
	Tube: ½” OD Copper 12 Rows			
	Fins: 0.13 thk x 12-13 Alu/inch			
7.0	**Steam Coil**			
	Tube : : ½ OD Copper 8Rows			
	Fins: 0.13 thk X 12 – 13 Alu /Inch			
8.0	**Coil Heater Size & Material :** ¾ Socket (BSP)			
9.0	**10 Micron Pre Filter**			
	Type: Flange type pleated			
	Size: 610 mm × 610 mm × 50 mm			
	Efficiency: 90% down to 10 micron			
	Qty: 1 Nos.			
10.0	**5 Micron Fine Filter**			
	Type : Flange type pleated			
	Size: 610 mm × 610 mm × 300 mm			
	Efficiency :95% down to 5 µ			
	Qty: 1 nos.			
11.0	**0.3 Micron HEPA Filter**			
	Type : Flange type HEPA			

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S.No.	Description	Observation	Observed By (Engineering) Sign/Date	Verified By QA Sign/Date
	Size: 610 mm × 610 mm × 300 mm			
	Efficiency: 99.99% down to 0.3 µ			
	Qty: 1 Nos.			
12.0	**WIP :** WIP Nozzles			
	Make: Solace Engrs. (Mktg.) Pvt. Ltd.			
	Type: Flood Jet 1.5 mm			
	Spray Rate: 50 LPM			
	MOC: AISI 304			
	Wash : Raw Water , Potable water, Purified Water			
13.0	**FLP Light:** 1 No.			
	Make: Prompt			
14.0	**Solution Tank With Agitator**			
	Make: Solace Engrs. (Mktg.) Pvt. Ltd.			
	Capacity: 75 Liter			
	MOC: AISI 316 L (Contact Parts)			
	AISI 304 (Non Contact Parts)			
	Qty : 1 No.			
15.0	**Agitator Air Motor**			
	Make: Tonson (Taiwan)			
16.0	**Peristaltic Pump**			
	Make: Thermofisher Scientific - USA			
	Model: 1900-1949,24 VDC			
17.0	**Peristaltic Pump Head**			
	Model: 77800 – 60			

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S.No.	Description	Observation	Observed By (Engineering) Sign/Date	Verified By QA Sign/Date
	Make: Masterflex L/S			
	No. of Head : 3 Nos. (Detachable)			
18.0.	**Exhaust Blower with Motor**			
	Make: RIB Engineers			
19.0.	**Spray Guns**			
	Make: Spraying System Co (USA)			
	Model: 1A-40-1/8 VAU316LSS			
	Qty.: 03 Nos.			
20.0	**Dampers**			
	Make: Solace Engrs (Mktg) Pvt. Ltd.			
	Actuator: Rotex (India) or Reputed			

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8.7 Safety:

Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
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 Guards	Guards for all moving parts Should be provided For safety		
Positioning	Auto Coater should be positioned as per drawing	\	
Pump for suction & discharge	Check the installation of pump for suction & discharge		
Inlet, exhaust air plenums & Positioning	Check the installation of inlet, exhaust air, plenums and plenum should not touching to pan		
Incoming airline connection to FRL unit	Check the installation of incoming airline to FRL unit and it should be installed properly		
Atomization airline	Check for proper installation of atomization airline		
Filters Placement	Check the installation of filters placed properly and no air leakage should be observed		
Oil Level in Gear box	Check gear box is filled with specified oil up to level		

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Sign/Date……

Inference:

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(Manager QA)
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.

The following references are used for addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

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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:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
MOC	:	Material of construction
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
mm	:	Millimetre
MCB	:	Miniature Circuit Breaker
V	:	Volts
DQ	:	Design Qualification
IQ	:	Installation Qualification
AHU	:	Air Handling Unit
P & ID	:	Piping & Instrumentation Diagram
V	:	Volt
M/C	:	Machine
KW	:	Kilo Watt
HEPA	:	High Efficiency Particulate Air
WIP	:	Wash in Place
DM	:	De mineralized
VFD	:	Variable Functioning Device
LMP	:	Liter per minute

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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