



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
COATING PAN 36"**

<b>EQUIPMENT ID No.</b>	
<b>LOCATION</b>	<b>Coating Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**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)			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of Coating Pan means “The process conforming that an item of equipment, or other system, as currently installed, meets its design qualification”.
- To provide documented evidence for the Installation Qualification of Coating Pan.
- 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 and complies with cGMP and cGEP practices.

**3.0 SCOPE:**

- The scope of this Installation Qualification Protocol cum Report is limited to qualification of **Coating Pan (Make: Sehgal Engineers) (Pan Diameter: 36 Inch, Capacity: 80 Kg)** to be installed.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Coating Pan.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post approval of qualification Protocol cum Report after execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Coating Pan Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Qualification Protocol cum report after Execution.</li></ul>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36"**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Coating Pan
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Location of Installation</b>	Coating Area

**6.0 SYSTEM 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.



## **INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

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

### **7.0 PRE – QUALIFICATION REQUIREMENTS:**

#### **7.1 Verification of Documents:**

- Executed and approved design qualification document.
- 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.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Installation Qualification Checklist:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Grouting and Mounting</b>	Should be properly grouted and mounted.		
<b>Leveling</b>	Should be properly balanced and leveled.		
<b>Edges of parts</b>	Metal parts should be properly ground without any sharp edges.		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
<b>Place of Installation</b>	Coating Area ‘G’ Block.		
<b>Room Condition</b>	General Room Conditions.		
<b>Illumination</b>	NLT 300 Lux.		
<b>Working space around the Equipment.</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**Checked By  
(Production)**

**Sign/Date:** .....

**Verified By  
(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By  
(Manager QA)**

**Sign/Date:** .....





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**8.2 Technical Specification:**

<b>Component</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed by (Engineering) Sign/Date</b>
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.		
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 90° for easy cleaning/washing. Spray pattern (angle) can be controlled manually.		
Coating Application System	It contains 1 No., 1 liter solution holding vessel (SS 316) connected with the spray gun.		
Drive Assembly	Consists of a suitable 1 HP 3 Phase, 440 V and 1440 RPM TEFC motor with suitable worm reduction gearbox and cone pulley arrangement to give three-speed output.		
Dust Collector	Exhaust air is passed through dry scrubbing system, comprises MS scrubber with inlet and outlet connections, fed through series of cartridge filter.		
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		



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Component	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
Blower	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.		
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.		
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.		
Finish	All joints Argon Arc welded and all SS Parts polished to suitable finished required for smooth finish.		
RPM of Pan (Empty)	12-35 RPM		
Pressure Gauge	Make : TECHNO Range : 0 - 10 kg/cm <sup>2</sup> or 0 - 150 psi.		
Pneumatic FRL Unit	Make : TECHNO Quantity : 02 Nos. Model : AW4000-04, AL4000-04 Pressure : 0.15 - 0.85 Mpa		
Temperature	Make : SELEC		



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Component	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
Controller	Type : TC 303		
MCB	Make : L & T Model : BB3032OC Type : C32-240/415 V		
Loading Capacity	60-80 Kg		

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**(Quality Assurance)**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**8.3 MOC Verification List:**

S.No.	Component	MOC	Observation	Observed by (Engineering) Sign/Date
1.	Coating Pan	SS 316		
2.	Solution Holding Vessel	SS 316		
3.	Guns Nozzle, Cap, Needle	SS 316/SS 304		
4.	Operating Panel	SS 304		
5.	Power Panel	MS Powder Coated		
6.	Tubing's	Silicon		
7.	Spraying Arm	Silicon		
8.	Blower Impeller	MS		

**Checked By  
(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

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**Reviewed By  
(Manager QA)**

**Sign/Date:** .....



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**8.4 Utility Verification List:**

<b>Critical Variables</b>	<b>Acceptance criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Electrical Supply</b>	Voltage : 440 V, kW : 3.0 kW, Phase : 3 Phase, Frequency : 50 Hz.		
<b>Room Condition</b>	Temperature and RH required as per requirement of product.		

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Sign/Date: .....**

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(Quality Assurance)  
Sign/Date: .....**

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(Manager QA)  
Sign/Date: .....**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**8.5 Safety:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed by (Engineering) Sign/Date</b>
<b>Mechanical Guard</b>	Mechanical guard for all rotating parts.		
<b>Lubrication</b>	Proper grease in the bearing housing should be available.		
<b>Dimensional Accuracy</b>	Dimensionally accurate.		
<b>Inlet, Exhaust Air Plenums</b>	Check the installation of inlet, exhaust air plenums are not touching to pan.		
<b>Incoming Airline Connection to FRL Unit</b>	Check the installation of incoming airline connection to FRL Unit.		
<b>Electrical Wiring and Earthing</b>	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.		

**Checked By (Production)**  
**Sign/Date:** .....

**Verified By (Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By (Manager QA)**  
**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**9.0 REFERENCES:**

**The Principle References 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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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36"**

**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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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”**

**16.0 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
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



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**17.0 PROTOCOL POST 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)			