OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

COATING PAN 36”

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

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OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR COATING PAN 36”

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the Operational features of Coating pan and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Equipment, Cleaning Procedure and Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Protocol cum Report is limited to Operational Qualification of **Coating Pan (Make:** Sehgal Engineers**) (Pan Diameter:** 36 Inch**, Capacity:** 80 Kg**)**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of the Coating pan.
- Successful completion of this Protocol cum Report will verify that Coating pan meet all acceptance criteria and ready for Performance 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	• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post approval of Operational Qualification Protocol cum Report after execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post approval of Operational Qualification Protocol cum Report after execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Coating Pan 36”
Equipment ID.	
Manufacturer’s Name	Sehgal Engineers
Supplier’s Name	Sehgal Engineers
Location of Installation	Coating Area

6.0 EQUIPEMENT 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

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S. No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for Operation & Cleaning of Coating Pan.			
4.	SOP for Preventive Maintenance of Coating Pan.			

7.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment / Instrument I.D.	Calibration On	Due On	Observed By (Sign/Date)

Checked By
(Production)
Sign/Date: ……

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks:

Operate the Coating Pan as per Manufacturer’s Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

8.1.1 ON/OFF Operation:

Process	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Press ON Switch, machine start.	By pressing ON switch machine should start.		
Press OFF Switch, machine stop.	By pressing OFF switch machine should stop.		

8.1.2 Pan Speed Limit Checking:

Process	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Set pan speed at 1 RPM as minimum set point.	The pan shall run at 1 RPM (Minimum).		
Set pan speed at 7 RPM as maximum set point.	The pan shall run at 7 RPM.		
Reset the pan speed to a mid range value & Record the value, **Press the emergency stop.** **Restart the machine/pan allows the speed to stabilize and record the RPM.**	Pan speed shall be the same before and after the power cut off.		

8.2 Safety Testing/Interlocking Checks:

Item	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.		
Motor Overload Relay	The switchgear shall trip if overloaded.		
Start Push Button	Machine START		
Stop Push Button	Machine STOP		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Emergency Operation Verification:

Process	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Press the emergency stop located on the control panel body.	All pneumatic supplies shall be de energized.		
With the emergency stop	All motors stop.		
With the emergency stop pressed check the condition of the valve solenoid indicator in the pneumatic panel.	All solenoid indicators shall be extinguished.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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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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:

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
PQ	:	Performance 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

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)			