PERFORMANCE QUALIFICATION

PROTOCOL

FOR

COATING PAN 36”

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

PERFORMANCE QUALIFICATION PROTOCOL FOR COATING PAN 36”

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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 provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for **Coating Pan (Make:** Sehgal Engineers**) (Pan Diameter:** 36 Inch**, Capacity:** 80 Kg**)** installed.
- This Protocol will define the methods and documentation used to qualify the Coating Pan for PQ.

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, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing / Analysis)
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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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 EQUIPMENT 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 REASON FOR QUALIFICATION:

- New equipment in Coating Area.
- After completion of the Operational Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

- Coating Area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two year.
- After any major breakdown or after major modification.
- After Change of Location.

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10.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Preparation of SOP for Operation & Cleaning of Coating Pan.
- Preparation of SOP for Preventive Maintenance of Coating Pan.

11.0 TESTS AND CHECKS:

11.1 EVALUATION OF MACHINE SPEED:

The following test shall be carried out to establish qualification of “Tablet coating”.

Objective:

To establish the coating pan RPM and coating time at fix inlet and exhaust CFM and temperature (Operational) for smooth running and confirmation of the establish standard parameter.

Procedure:

- The test should be carried out in triplicate.
- Switch “ON” the machine and operate as per SOP.
- Load the product batch and in coating pan and set the following parameters as required for the selected product
- Run the coating pan as per above fix parameter and collect the sample at different locations at different intervals

11.2 PERFORMANCE EVALUATION USING PLACEBO FORMULATION:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish the performance based range of operating parameters for performance qualification activity using drug product.

11.2.1 Procedure:

- Load Placebo formulation in the range of 80 % of capacity to the pan of Coating Pan.
- Perform Coating at optimized coating parameters.

- Collect samples of coated products from 3 different locations after completion of coating process.
- Analyze collected sample for Description, Dimension, Average Weight, % Weight gain, individual weight variation and % variation.

11.2.2 Acceptance Criteria:

- Sample collected from different locations should have uniform result for all the analyzed test parameter.

11.3 PERFORMANCE EVALUATION USING DRUG PRODUCTS:

- To verify the performance of Coating Pan in the established operating range.
- To establish documented evidence that the Coating Pan is performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of coated products.

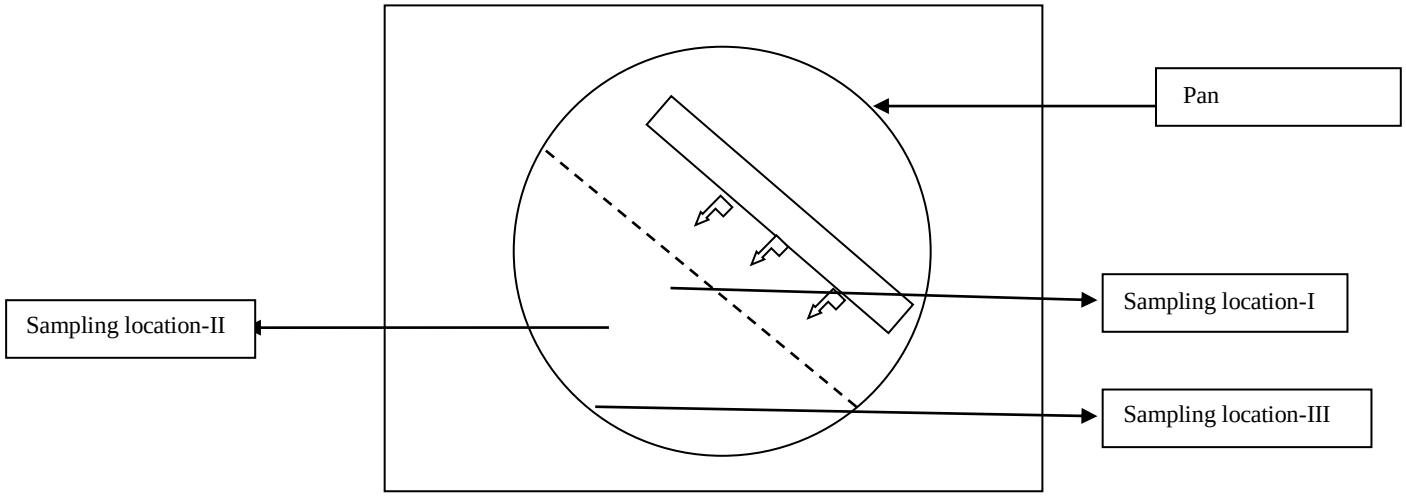
11.3.1 Procedure:

- Coating shall be performed on 3 different batches of same or different products.
- Load the product to the pan of Coating Pan.
- Perform coating at coating parameters as specified in the BMR of product.
- Collect samples of coated products from 3 different locations after completion of coating process.
- Analyze collected sample for Description, Dimension, Average Weight, % Weight gain, individual weight variation and % variation.

11.3.2 Acceptance Criteria:

- All the samples of different locations should meet the pre - defined acceptance criteria of coated products.

11.4 SAMPLING PLAN:



12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of performance using placebo formulation.
- Verification of performance using Drug product.

13.0 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**.**

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, Specifications, Sampling, Analysis and Documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
P & ID	:	Piping and Instrumentation Diagram
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
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
RH	:	Relative Humidity