PERFORMANCE QUALIFICATION

PROTOCOL

FOR

AUTO COATER - 37”

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

PERFORMANCE QUALIFICATION PROTOCOL FOR AUTO COATER - 37”

PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR AUTO COATER - 37”

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
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 established operating range and the results of all the test parameters meet the acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- This protocol covers all aspects of Performance Qualification of **Auto Coater (Solace Engineers Pvt. Ltd., 37”)** installed in the Coating.
- This Protocol will define the methods and documentation used to qualify the Auto Coater 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	• Initiation, Approval Compilation and Authorization 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	• Review of Protocol.
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	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

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7.0 REASON FOR QUALIFICATION:

- New equipment in Coating area.
- After completion of the Operation 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 two year time period.
- After any major breakdown or after major modification.
- After Change of Location

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
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operating & Cleaning of Auto Coater.
- Preparation of SOP for Preventive Maintenance Auto Coater.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document
- Executed and approved Installation Qualification document
- Executed and approved Operational Qualification document
- SOP for operating & Cleaning of Rapid Mixer Granulator
- SOP for Preventive Maintenance Rapid Mixer Granulator.

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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

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 Auto Coater.
- 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 and % of Weight gain.

11.2.2 Acceptance Criteria:

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

11.3 PERFORMANCE EVALUATION USING DRUG PRODUCTS:

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

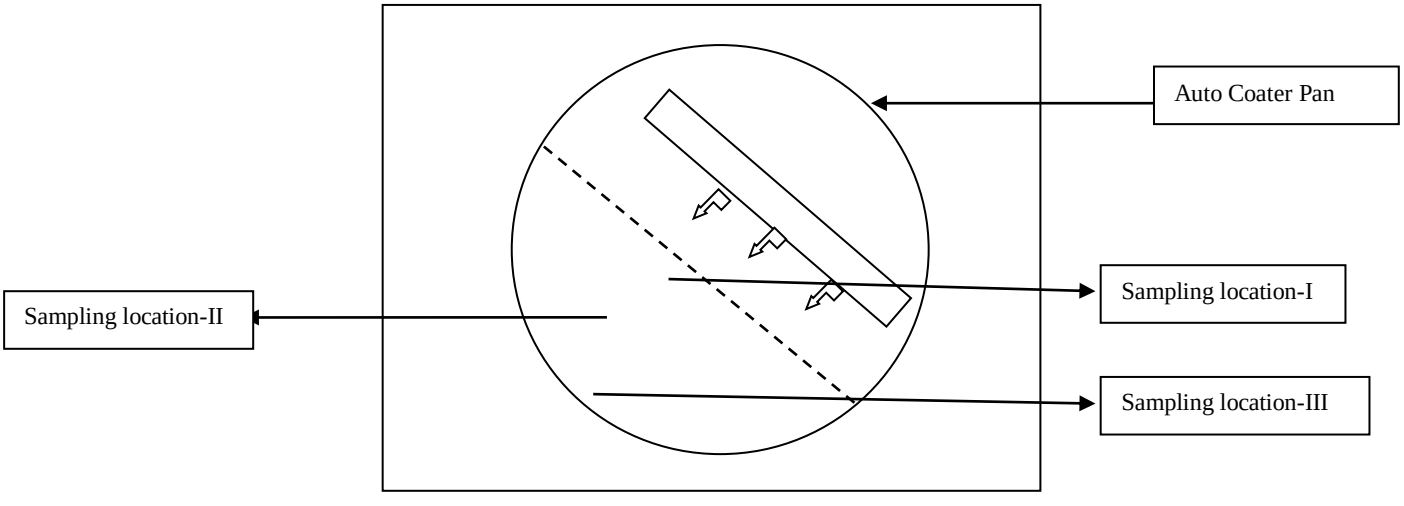
11.3.1 Procedure:

- Coating shall be performed on 3 different batches of same or different products.
- Load the product to the pan of Auto Coater.
- Perform coating at coating parameters as specified in the BMR of product.
- Collect samples from different locations after completion of coating process and Check the in process.

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 DQ, IQ & OQ & other documents.
- Verification of performance using placebo formulation.
- Verification of performance using Drug product.

13.0 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Operation and Maintenance Manual.

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:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
mm	:	Millimeter
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
BMR	:	Batch Manufacturing Record
SOP	:	Standard Operating Procedure