OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

AUTO COATER - 37”

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

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OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTO COATER - 37”

2.0 OBJECTIVE:

- To provide documented evidences for Operational Qualification of Auto Coater (Make – Solace Engineers Pvt. Ltd., 37”) installed in the Coating.
- To verify all the Operational features from user friendly point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to the qualification of **Auto Coater (Make – Solace Engineers Pvt. Ltd., 37”)** installed in the Coating.
- This Protocol will define the methods and documentation used to perform OQ activity for the Auto Coater. Successful completion of this Protocol will verify that Auto Coater 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	• Initiation, Approval Compilation and Authorization of the Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operation Qualification Protocol after Execution
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Dispensing Booth Operational 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
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 OQ 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 Documents Verification:

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for operating & Cleaning of Auto Coater				
4.	Draft SOP for Preventive Maintenance of Auto Coater				

Checked By
(Production)
Sign/Date: ……

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

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

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. 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

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8.3 Operational And Functional Checks:

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

Process	Acceptance Criteria	Observation	Observed By (Engineering) Sign
Press the emergency stop located on the control panel body.	All pneumatic supplies should be de energized and appropriate alarm shall be displayed.		
With the “emergency stop pressed” check the PLC out put	All PLC output should be de - energized		
With the emergency stop	All motor and moving parts should be stopped		
With the emergency stop pressed check the condition of the valve solenoid indicator in the pneumatic panel	All solenoid indicator should be extinguished		
On the console with the emergency stop pressed. Reset the emergency stop switch check the condition of the PLC outputs.	The PLC outputs should remain de energized		
On the console acknowledge any alarm and press the system release switch. Located by the data panel. Check the condition of the PLC outputs	The PLC outputs should be energized		

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8.4 Speed Verification of Components:

S.No.	Components	Specified RPM	Observed RPM	Observed By (Engineering) (Sign)
1.	Pan Motor	1420		
2.	AHU Motor	2830		
3.	Peristaltic Pump	Speed – I		
		Speed – II		
		Speed – III		

4. Pan	Set Speed	Display on PLC	Observed RPM	Observed By (Engineering) (Sign)
Speed – I				
Speed – II				
Speed – III				

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8.5 INLET TEMPERATURE (DATA ENTRY LIMIT CHECKING):

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Attempt to enter and 30°C. As inlet temp. set point	The system shall enter the set value		
Attempt to enter 85° C. As the inlet temperature set point	The system shall enter 85° C Maximum or set value.		
From the MMI console turn the pan light ON	The pan light shall turn ON		
Form the MMI console turn the pan light OFF	The pan light shall turn OFF		

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8.6 PAN FUNCTIONS:

8.6.1 PAN SPEED CONTROL/PERFORMANCE:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Adjust the pan speed, set point to mid-range value	The control shall accept the set point		
From the MMI start he pan in Manual mode only	The pan will start to rotate and will achieve the regulated speed		
Check that the MMI indicates that the pan is running	MMI indicates that the pan is running.		
Now adjust the pan speed to minimum range value(I.E 1 RPM)	Pan shall stabilize the minimum range value.		
Reset the pan speed set point to a mid range value- record the value press the emergency stop. Restart the machine/pan allows stabilizing the speed and record	Pan speed shall be the same before and after the power cut off.		

8.7 EXHAUST FAN SYSTEMS:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
From MMI start the exhaust fan	Exhaust fan starts rotating and it indicates.		
Now operate stop exhaust fan from MMI	Exhaust fan stops		

8.8 EXHAUST FAN CONTROL ALARM SYSTEM AND INTERLOCKS:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
With the exhaust fan running trip the exhaust fan motor circuit breaker	The exhaust fan shall come to a standstill and an alarm shall be generated.		
With the exhaust fan running. Turn the exhaust fan motor isolator off from MMI	The exhaust fan shall come to a stand still		

8.9 INLET FAN SYSTEM:

8.9.1 INLET FAN START/STOP:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Start the exhaust fan. Attempt to start the inlet fan	The inlet fan shall start to rotate. A press shall be required.		
With the inlet fan rotating from the MMI. select inlet fan stop	The inlet fan shall come to a standstill a press shall be required.		

8.10 INLET FAN SYSTEM INTERLOCKS:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
With the inlet and exhaust fan running from the MMI stop the exhaust fan	The exhaust and inlet fan shall come to a standstill		
With the system in wash mode attempt to start the inlet fan	The inlet fan shall no start.		

8.11 INLET FAN SYSTEM ALARMS:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
With the exhaust fan and inlet fan running. Trip the inlet fan motor circuit breaker	The inlet fan shall come to a standstill and alarm shall be generated.		
With the exhaust and inlet fans running. Turn the inlet fan motor isolator OFF form MMI	The inlet fan shall come to a standstill and an alarm shall be generated		

8.12 INLET TEMPERATURE SYSTEM:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Enter a set point for inlet temperature monitor the inlet temperature	The inlet temperature shall remain at ambient condition		
Start the exhaust and inlet fans monitor the inlet temperature allow the system to stabilize and record the indicated inlet temperature	The inlet temperature shall be controlled to the set point		
Adjust the inlet temperature to the maximum control set point	The inlet temperature shall be controlled to the set point		
Adjust the inlet temperature to the minimum control set point	The inlet temperature shall be controlled to the set point		
With the inlet temperature control active stop the inlet fan	The inlet temperature controller shall be deactivated		

8.13 EXHAUST TEMPERATURE PROCESS ALARM (HIGH):

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Enter a value for high inlet temperature	No alarm message will generate		
Start the exhaust fan and inlet fan allow the inlet temperature to stabilize when the inlet temperature has stabilized change the set point by 24 º C. Allow the system to stabilize and reset the inlet temperature to the previous exhaust temperature	The inlet temperature shall stabilize at the set point. The inlet temperature shall stabilize at the new value and no alarm shall be generated.		
When all the system parameters are stable. Switch the system to alarm mode.	The drum shall continue to rotate normally.		
Allow the exhaust temperature to stabilize at the new value record this as set point	The system shall stabilize at the new set point within the acceptable tolerance.		
Acknowledge the indicated temperature	System shall show that the alarm has been acknowledged.		
Check the system mode	The system shall be in start mode		

8.14 SPRAYING ENABLE FUNCTION:

Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
Activate the drum. Attempt to start the spraying system.	Pan shall rotate the spraying system shall no start.		
Activate the exhaust attempt to start the spraying system. Set the Min. Bed Temp	The exhaust fan shall start. The spraying system shall not start.		
Activate the inlet fan. Attempt to start the	The inlet fan shall start. The spraying system shall start after reaching the Bed		

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Process	Acceptance Criteria	Observation (Pass/Fail)	Observed By (Engineering) Sign & Date
spraying system			
Check the MMI indication for spraying enable. Set the Min. Exhaust temp within range	The system shall indicate that the spraying enable is on provided 1. Pan motor –ON 2. Exhaust Fan –ON 3. Inlet fan –ON 4. Compressed air pressure is more than set pressure. 5. Exhaust temp. is more than set temperature		

8.15 SAFETY TESTING/INTERLOCKING:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Electrical Wiring And Earthing	Must be inside the machine		
Motor Overload Relay	The switchgear shall trip if overloaded		
Emergency Off	To stop the process immediately		
Start Push Button	Machine START YES/NO		
Stop Push Button	Machine STOP YES/NO		
Emergency button	To stop M/C immediately YES/NO		

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Sign/Date: ……

8.15.1. 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.		

8.16 EMERGENCY OPERATION VERIFICATION:

Item	Acceptance criteria	Observation	Observed By (Engineering) (Sign/Date)
Emergency Stop • **Press Emergency Stop Push Button.**	Equipment should stop.		
• **Release Emergency Stop Push Button.**	Equipment should start.		
With the Emergency Stop Pressed in, try to cause movement of an Operating function.	The Equipment will be inoperative.		

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Sign/Date: ……

Inference:

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Reviewed By
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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.
- Calibration certificates.
- Operation and Maintenance Manual.

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
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

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

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