OPERATIONAL QUALIFICATION PROTOCOL

CUM REPORT

FOR

TABLET COATER

Equipment ID	
Equipment Location	
Equipment Make	**Pam Glatt**
Document No.	**OQ/**
Reason For Qualification	**New Equipment**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER	PROTOCOL No.:

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1.0 PRE-APPROVAL

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER	PROTOCOL No.:

Signing of this Operational Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Signature	Date
Production			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Organization	Name	Signature	Date
Head Engineering			
Head Manufacturing			

2.0 OBJECTIVE

The objectives of this Operational Qualification (OQ) are as follows:

- 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 confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

Following execution of the protocol a summary report will be written and approved. All results, conclusions, exceptions and variances will be addressed and final disposition of the equipment will be stated. Successful completion of this protocol and approval of the summary report will verify that the Tablet Coating System meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE

This protocol covers all aspects of Operational Qualification for the Tablet Coating System serving Tablets, Capsules and Dry syrup Dry Powder Injection Oral Manufacturing Facility. Scope incorporates qualification of all Tablet Coating System components from Inlet air Handler with HEPA filter through Tablet Coating System with product filter, up to and including Exhaust blower, spray system including solution tank, pump & spray nozzles.

This protocol will define the methods and documentation used to qualify the Tablet Coating System for OQ. Successful completion of this protocol will verify that the Tablet Coating System meets all acceptance criteria and is ready for Performance Qualification.

4.0 RESPONSIBILITIES

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff.

Department	Responsibilities
Production	Prepare, check and approve the Operational Qualification Protocol.
	Distributes the finalized protocol for check, approve and authorization signatures.
	Execution of Operational Qualification Protocol.
	Complied qualification data package, and final report.
Engineering	Check, approve and execution of Operational qualification protocol.
Quality Assurance	Check the protocol for operation of equipments.
	Final authorization of protocol.

5.0 SYSTEM DESCRIPTION

The Tablet Coating System and its associated equipment are designed to process pharmaceutical products in accordance with cGMP principles. The Tablet Coating System is used for coating tablets with aqueous or non-aqueous solvents

Conditioned Air is drawn through the Tablet Coating System by a Variable speed drive blower. The air is supplied from the Service area and conditioned and filtered by the Inlet air handling Unit (AHU) located within the Service area.

Qualification activities for the Tablet Coating System incorporate the following system components:

- Inlet air handling unit
- Coating Pan
- Spray system including solution tank, pump & spray nozzles
- Exhaust air blower

The inlet air-handling unit filters the fresh air through insect screen, EU-4 grade pre-filter and EU-5 grade filter prior to heating it to required temperature. The hot air is finally filtered through HEPA filter, EU-13 grade, and delivered to Tablet Coating System. Perforated coating pan is provided for allowing hot air to pass through. The pan has baffles that help the tablets to move in a very uniform pattern, thereby receive a uniform coating.

The spray system consists of a solution vessel with stirrer, a peristaltic pump and spray nozzle assembly. Silicone tubes are used

to transfer material from the solution vessel to the spray nozzle, via the peristaltic pump. The atomisation of spray solution is achieved by providing high pressure compressed air to the atomising spray nozzles. The spray rate and the atomising pressure can be controlled from the operator's panel. Exhaust air blower is present to draw the air out from the system Associated System components comprise:

- PLC Control System: The Tablet Coating System is controlled and monitored via a PLC (Programmable Logic Controller) and Industrial type Human Machine Interface (HMI). All the major parameters including Alarms will be through control panel.

6.0 DOCUMENTATION REQUIREMENTS

The OQ File should include:

- This OQ Protocol.
- Any laboratory test results or their referenced location.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All personnel shall have suitable documented training or experience.
All approvals shall be made in *BLACK* ink.
All data entry shall be made in *BLACK* ink.
All corrections to this Protocol, which are not retyped, are to be made in *BLACK* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the qualification tests, collect all relevant printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Annexure* and to be listed in *Section 14 List of Annexure*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the ALL Project Change Control Procedure (SOP No: …….).
Change Control Forms raised during the execution of this OQ will be filed along with the protocol. An assessment will be made for each change to determine whether or not any re-validation is required.

9.0 PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations (as per CQA/032) or issues should be rectified and documented prior to OQ commencing. Open action items resulting from these tests shall be listed in the Comments section. System Pre-requisites

S.No.	Description of Pre-requisite	Completed Yes or No	Verified By	Date
1	Verify that the IQ of the Tablet Coating System has been executed and approved. IQ Protocol Document No:	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Tablet Coating System has been executed and approved.	Yes/No*		
3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
4	SOP of Tablet Coating System Operation and cleaning	Yes/No*		

Note:- * -Circle one, which is appropriate.

10.0 TESTS AND CHECKS:

10.1 SOP Verification

10.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Tablet Coating System.

10.1.2 Method

Obtain a controlled copy of each SOP referenced within section 10.1.4. During the course of OQ testing, perform each operation according to the instruction indicated within the appropriate SOP. Mark with a highlighter pen each instruction or statement within the SOP which is verified and in accordance with the actual practice. Write any differences from actual practice in red ink on the copy of the SOP. On completion, write "Operational Qualification - SOP Verification" on the marked-up copy of the SOP, sign & date it and attach as an annexure to the OQ protocol together with any other raw data such as printouts.
Ensure all SOP's identified in Section 10.1.4 are evaluated and checked.

10.1.3 Acceptance Criteria

At the completion of OQ testing, all standard operating procedures referenced within section 10.1.4 will be annotated to correctly reflect the applicable method instruction(s) required to obtain intended operation or function result.

10.1.4 Results

Enter the SOPs into the table below and verify that they have been evaluated and checked. Incorporate the marked up SOP's as an appendix to the OQ report together with any other raw data such as printouts

SOP Number	SOP Description	SOP accurate after check [Y/N]	Initial / Date
	SOP-Tablet Coating System Operation and cleaning		

Comments:

Reviewed by		Date	

10.2 Input / Output (I/O) Test

10.2.1 Objective

To verify that PLC Inputs and Outputs (I/Os) are connected to the correct field device.

10.2.2 Method

Input/output checks have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document . Ensure that all tasks have been completed and signed off as correct.

Check the machine operation either by forcing the signal or by checking the sequence of machine operation.

10.2.3 Acceptance Criteria

SAT must show that all field devices operate and communicate correctly with the control system in agreement with the electrical schematics. Therefore, verify that all testing was witnessed, completed and signed off as correct.
Where I/Os have been re-tested, verify that all field devices operate and communicate in accordance with the control system and in agreement with associated electrical schematics.

Check sheet of individual I/Os re-tested are attached in annexure.

10.2.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify Input/Output Tests have been Completed as specified in SAT document -	Tests have been witnessed, completed and signed off as correct.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.3 System Security Test

10.3.1 Objective

To verify that access to system programs and data are protected in an adequate manner.

10.3.2Method

Follow instructions in the Test Method column in section 10.3.4 to test security of the system. Record all observations in the actual results column in section 10.3.4 and attach any raw data printouts as an annexure to this protocol.

10.3.3Acceptance Criteria

Access to control system and software is to authorised personnel only. Specific acceptance criteria for each test are provided in section 10.3.4.

10.3.4Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Enter test methods for testing in-built security access to the control system	Three level password for Manager, Supervisor and Operator.			
Attempt to access PLC.	Physical restriction by lock to an unauthorised user is in place.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.4 System Start-Up and Shutdown Test

10.4.1 Objective

To verify that the system components will power-up and start as defined by the design documentation.

10.4.2 Method

Follow instructions in the Test Method column of section 10.4.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an annexure to this protocol. Record all observations in section 10.4.4 and attach any raw data printouts as an annexure to this protocol.

10.4.3 Acceptance Criteria

All Start-up and Shutdown functions operate correctly as specified in the following document:

- *System Operating and Maintenance Manual* Tablet Coating System

Specific acceptance criteria for each test are provided in the tables in section 10.4.4.

10.4.4 Results

10.4.4.1 Shutdown Procedure

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
While the system is operating, cease operation by assigning the following mode on the Human Machine Interface (HMI):				
Stop inlet AHU fan	AHU fan stop. Indication through in HMI.			
Operate Inlet damper	Close Indication appear in HMI			
Operate exhaust blower	Stop indication appear in HMI for RPM			

Operate exhaust damper	Close Indication appear in HMI			
Operate Pan motor	Stop indication appear in HMI			
	Indication appear in HMI for Pan RPM drops to zero			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.4.4.2 Power-Up and Start Test

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Start operation by turning on the main power isolator at the Tablet coating system Control Panel and power up the pneumatic panel.	Power is distributed to electrical components in control and pneumatic panel. System returns to operation mode.			
Operate Inlet damper, Exhaust damper.	Open Indication for inlet appear in HMI			
	Open Indication exhaust appear in HMI			
Operate exhaust blower	Indication appear in HMI for set RPM			
Start inlet AHU Fan	AHU fan starts operating with indication in HMI.			
Operate Pan motor	Prior to operate motor ensure that pan bed with 5 no's removable baffles with spray nozzle are in place.			
	Indication appear in HMI for Pan RPM			
Start Peristaltic pump and spray liquid through spray nozzle	Indication appear in HMI for pump RPM			
	Pressure required for atomisation indicated in pressure gauge mounted on pneumatic panel			

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Comments:

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10.5 Operator Data Entry Test

10.5.1 Objective

To verify system response following Operator Data Entry and to ensure that the system will only accept approved inputs and that all other inputs are rejected in a controlled manner.

10.5.2 Method

Follow the instruction within the test method column of section 10.5.4 to test the data entry of the system. Record all observations in the actual results in section 10.5.4 and attach any raw data printouts as an annexure to this protocol.
Ensure that upon test conclusion, all parameter set points are returned to normal operating status.

10.5.3 Acceptance Criteria

Operator inputs with limits / formats associated with them will accept values as stated in column "System accepts Input as Valid". Entered value or format stated in column "System rejects Input as invalid" will be rejected by the system.

10.5.4 Results

System Variable	Limits		Value Smaller than Min	Value Greater than Max	Expected Result Met?	
	Min	Max			Yes/No	Initial & Date
Expected Result	System accepts Input as Valid		System rejects Input as Invalid			
DP Transmitter across inlet HEPA filter	-50	0	-51	1		
DP Transmitter across Coating Pan	-50	0	-51	1		
Temperature Transmitter	0	150	-1	151		
RH Sensor at inlet air line	0	150	-1	151		
Temperature Transmitter inlet air.	0	150	-1	151		
Temperature Transmitter-exhaust air temperature	0	150	-1	151		

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.6 System Functionality Tests

10.6.1 Objective

To verify Tablet Coating System components functionality.

10.6.2 Method

Prior to this test, power up and start-up each component as described in Section 10.4.4 Power *Up and Start Test.* Operate each item as described in Section 10.6.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 10.6.4.

10.6.3 Acceptance Criteria

All aspects of control for individual components integrated within the Tablet Coating System shall function as specified in the expected results column in Section 10.6.4.

10.6.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
Switch on the power & utilities to Tablet coating system	Machine is ready to start.			
Monitor and Log the readings.	Log the following readings: 1. Voltage. 415 ± 10 %Volts 2. Compressed air pressure – 6.0 Kg/cm^2. 3. Steam Pressure – 3.1 kg /cm^2. 4. Chilled water at 6 to 8 °C and 2.5 kg /cm^2.			
Operate exhaust blower	Indication appear in HMI for CFM			
Start inlet AHU Fan	AHU fan starts operating. Indication through HMI.			
Visual inspection of rotating pan assembly Fan	Ensure that pan bed with 5 no's removable baffles with spray nozzle are in place.			
Operate Pan motor	Indication appear in HMI for RPM			
Operate pneumatic stirrer	Visually Ensure that stirrer starts.			
Start Peristaltic pump and spray liquid through spray nozzle	Indication appear in HMI for pump RPM			
	Pressure required for atomisation indicated in HMI mounted on pneumatic panel			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.7 System Alarm and Interlocks Test

10.7.1 Objective

To verify that operation of system alarms and interlocks are functioning correctly.

10.7.2 Method

Tablet Coating System Alarm Tests have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document . Ensure that all tasks have been completed and signed off as correct. State this in the section below and refer to the relevant supporting documentation in the Actual results column.

With a copy of the SAT document and relevant sections of the Software Design Specification for the Tablet Coating System, re-test 10% of all alarms in accordance with the method described in the SAT. List down the names of individual alarms and interlocks re-tested on a check sheet. Verify on the check sheet that the alarm/ interlock has passed or failed.

If there are no failures when testing 10% of the alarms, then alarms testing are complete. Record results in section 10.8.4. Should there be a failure of one or more alarm proceeds to re-test 50% of all alarms in the manner described above. If no failures are found while checking 50% of the alarms, then alarms testing are complete. Record results in section 10.7.4. If there are one or more failures while testing 50% of the Alarms, proceed to test 100% of the Alarms in the manner described above.

Note: Only test the alarms / interlocks that will not result in any physical/ structural damage to the system as a result.

10.7.3Acceptance Criteria

SAT document must show that the system alarms/ interlocks activate in the correct situation and with the correct effect.

Alarm / Interlock retesting must activate in the correct situation and with the correct effect as described in the SAT document.

System cannot be started when critical alarms are activated.

Record of alarms/interlocks testing check sheet is attached in the annexure.

10.7.4Results

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Air Pressure minimum	Input the test method to trigger the alarm	Alarm generated and machine trips.			
Inlet Temperature less than minimum		Alarm generated.			
Exhaust Temperature less than minimum		Alarm generated.			
AHU Fan overload		Alarm generated.			
Exhaust Temperature more than set point		Alarm generated.			
Process time end		Alarm generated			
Inlet Temperature more than maximum.		Alarm generated and machine trips.			
Guard open		Alarm generated.			
Spray Air Pressure		Alarm generated. Peristaltic pump stops.			
DP Pan minimum /maximum/ sensor failure		Alarm generated			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.8 System Emergency Shutdown Stop

10.8.1 Objective

To verify that the emergency stop function activation shuts down the system in an appropriate manner.

10.8.2 Method

Ensure system is running under normal operating procedures. Press the emergency stop button and follow instructions in the Test Method column in section 10.8.4. Record all observations in the Actual Result column in section 10.8.4 and attach any raw data printouts as an appendix to this protocol.

10.8.3 Acceptance Criteria

Component comprising the system shut down in a safe and controlled manner when the emergency stop button is pressed. All pumps and motors will trip. An alarm condition is registered with audible alarm.

10.8.4Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial /Date
Press Emergency Stop Button while the system is running in normal operating mode	The Process Stop in a safe and controlled manner. showing on HMI			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.9 System Power Failure and Recovery Test

10.9.1 Objective

To ensure that system integrity is maintained in the event of power loss, that the system operates in accordance with specified

acceptance criteria during failure and that the system can be recovered back to a satisfactory operational state without the loss of data.

10.9.2 Method

Perform a simulated power loss while the systems operating normally without any faults. Verify the capability of the system to safely recover and resume normal operation. Verify that the system is able to retain the original program without data corruption. Also, verify that the system can prevent loss or corruption of stored data.

10.9 System Power Failure and Recovery Test

10.9.1 Objective

To ensure that system integrity is maintained in the event of power loss, that the system operates in accordance with specified acceptance criteria during failure and that the system can be recovered back to a satisfactory operational state without the loss of data.

10.9.2 Method

Perform a simulated power loss while the systems operating normally without any faults. Verify the capability of the system to safely recover and resume normal operation. Verify that the system is able to retain the original program without data corruption. Also, verify that the system can prevent loss or corruption of stored data.

Follow instructions in the Test Method column in Section 10.9.4. Record all observations in the Actual Results column in section 10.9.4 and attach any raw data printouts as an annexure to this protocol.

10.9.3 Acceptance Criteria

Upon loss of power the system shuts down safely without causing damage to equipment components and can automatically restart following a power failure event without the need for application of additional resetting procedures

The system is able to retain the original program upon a loss of power.

The system is able to prevent the loss or corruption of stored data during a power failure.

10.9.4Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Copy the list of set parameters from the HMI at the Configuration Menu before power failure test in Section 10.9.4.1 'Parameter Settings'. Perform a simulated power loss while the system is operating normally without any faults.	The system will automatically restart upon restoration of electrical power. The system will choose from which phase the plant has restart, depending on the parameters conditions at the power ON moment.			
Restore electrical power to the system.	The system steps through the start-up and normal operation phases identical to start-up test.			

After the restoration and recovery of electrical power, copy the list of set parameters from the HMI at the Configuration Menu in Section 10.9.4.1 'Parameter Settings'. Check the set parameters value before and after power failure. Verify that the system is able to retain original program without data corruption in case of power failure.	Parameters settings before and after power failure are the same.			

2.1.1.1 Parameter settings

System Variable	Prior to Power Failure	Following power restoration	Initial / Date
DP Transmitter across inlet HEPA filter			
Temperature Transmitter			
RH Sensor at inlet air line			
Temperature Transmitter inlet air.			
Temperature Transmitter-exhaust air temperature			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.10 Filter Integrity Test

10.10.1 Objective

To verify that installed filters have been integrity tested, and that certification remains valid within the period set forth for operational use.

10.10.2 Method

Review filter integrity test documentation for filters listed in section 10.10.4. Verify that the method used for testing was in accordance with ALL procedure, that test results conform to specifications contained therein, and that certification encompasses the period intended for operational use of the system.

Attach copies of integrity test printouts / reports for each filter and record results in Section 10.10.4. Record details of associated test equipment section 9.2 'Test Equipment Calibration' and attach calibration certificate copies as an annexure to this protocol.

10.10.3 Acceptance Criteria

Test methods comply with ALL procedure for 'Integrity Testing of Filters

All filters have been issued with ALL approved integrity test certificate that is valid for the period of operational use.

10.10.4 Results

Filter Installation location/description and Filter Tag No	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
HEPA filter	Meets criteria as per ISO - 14644.			
0.2 micron filter	Meets criteria as per ISO - 14644			

Comments:

Reviewed by		Date	

10.11 Operator Interface and Screen Graphics Testing

10.11.1 Objective

To verify the operation of all push buttons, touch buttons, switches and screen graphics associated with the Tablet Coating System.

10.11.2 Method

Verify that all push buttons, touch buttons and switches and screen graphics operate as defined in the tables. Document the results of the test in the table below. Record the results in section 10.11.4 of this protocol.
Verify and mark-up a copy of the following operator screens and attach the copy to the protocol

- Main Menu
- Inlet AHU
- Coating Pan Assembly
- Exhaust Blower
- Spray System

10.11.3 Acceptance Criteria

The pushbuttons touch buttons and switches operate as defined in the tables. The screen graphics appear as defined in the table. The actual results meet the expected results as defined in the test table(s) provided.

10.11.4Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Control panel				
Alarm sounder reset: Generate an alarm and press the Alarm sounder reset	The Audible alarm silences, but raised alarm is still active.			
Reset alarm button: Generate an alarm and press the Reset Fatal alarm button when the alarm condition has been lifted.	The alarm is reset and the alarm disappears from the alarm status 'active alarms' screen.			
Display or print each of the screens containing critical data, from the system HMI. Verify the screens against those specified.	The screens printed or displayed from the system, accurately represent the screens specified by the vendor documentation			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.12 Valve Operational Test

10.12.1 Objective

To ensure that valves located at throughout the Tablet Coating system operates correctly and can be accessed safely.

10.12.2 Method

Locate each valve listed in Section 10.12.4. Perform the test by manually opening and closing the valve. Verify that all valves can be accessed safely and that each valve can be fully opened and closed. Record results following testing in section 10.12.4.

10.12.3 Acceptance Criteria

Each valve can be accessed safely.
Each valve can be operated at full open and full closed positions.

10.12.4 Results

Valve Check	Expected Result	Valve Tag No	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.				

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.13 Confirmation of Critical Parameter and Full Function Testing

10.13.1 Objective

To confirm that the critical parameter and full function of the Tablet Coating System are as defined below:

- Non-metallic contact parts such as gaskets ‘O’ rings and other elastomers coming in contact with the product is of food grade quality.

- The lubricants used is food grade and they do not come into contact with product or product contact parts
- The machine trips if an inlet/exhaust air temperature crosses minimum / maximum limits.
- Spray system is calibrated to establish spray rate before coating. This is carried out before start up of system.

10.13.2 Method

Follow the test methods described in section 10.13.4 for various parameters under test.
Record the observation in 10.13.4 actual results column.
Attach supporting documents, as applicable, in the annexure.

10.13.3 Acceptance Criteria

The critical operational parameters and full function testing on the Tablet Coating System has been identified and completed satisfactorily.

10.13.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Product contact Parts				
O Rings & gaskets to be of Food Grade – Verification of Test Certificates	Material to Confirm Food Grade quality			
Lubricants are Food Grade & does not come in contact with the Product				
Visual Inspection & test certificates from Vendor	Lubricants are Food Grade & does not come in contact with the Product			
Inlet/Exhaust Air Temperature.				
Air temperature crosses maximum/minimum limit	Alarm generated.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.14 Loss of Utilities

10.14.1 Objective

To verify the loss of utilities supplies will not affect or damage the Tablet Coating System and that the subsequent return of any failed utility does not pose a threat to the system, the system's operator and the product quality.

10.14.2 Method

- **Steam Supply to the Tablet Coating System**
  Run the Tablet Coating System in normal operation.
  Isolate the supply of Steam to the system. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of Steam to the Tablet Coating System and record the systems reactions in the result table 10.14.4 as the system returns to normal operation
- **Compressed Air Supply to the Tablet Coating System**
  Run the Tablet Coating System in normal operation.
  Isolate the supply of compressed air to the Tablet Coating System. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of compressed air and record the systems reactions in the result table 10.14.4 as the system returns to normal operation

10.14.3 Acceptance Criteria

The Tablet Coating System shall raise an alarm and revert to the scenarios listed in the results section below on the isolation of:

- Steam Supply
- Compressed air

1014.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Shut off the Steam Supply to the Tablet Coating System. Record the system's reactions in the actual result column.	Alarm is generated			
Supply to the Tablet Coating System is restored. Record the system's reactions in the actual result column.	System is restored			
Turn off compressed air supply to the Tablet Coating System. Record the system's reactions in the "actual result" column.	Air pressure low			
	All actuated valves fail-safe			
	System shuts down			
Restore compressed air supply to the Tablet Coating System. Record the system's reactions as the system returns to normal operation.	System reverts to normal status.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.15 Automation Interface Tests

10.15.1 Objective

To verify that the interface between the control system and other automation is as defined.

10.15.2 Method

Follow the instructions in the Test Method column in the table to test the interface between the control system and other automation. Record all observations in the Actual Results section of the table.

10.15.3 Acceptance Criteria

The interface between the control system and other automation must be as defined in the expected result column within the table

10.15.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Disconnect the HMI communication cable.	HMI screen to become blank and message will appear that communication signal is missing.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

11.0 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
10.1	SOP Verification		
10.2	Digital Input & Output Test		
10.3	Tablet coating System Security Test		
10.4	Tablet coating System Start-Up and Shutdown Test		
10.5	Operator Data Entry Test		
10.6	Tablet coating System Functionality Test		
10.7	Tablet coating system Alarm and Interlocks Test		
10.8	Tablet coating system Emergency Shutdown Test		
10.9	Tablet coating system Power Failure and Recovery Test		
10.10	Filter Integrity Test		
10.11	Operator interface and Screen Graphics Testing		
10.12	Valve Operational Test		
10.13	Confirmation of Critical parameter and full function testing		
10.14	Loss of utilities		
10.15	Automation Interface test		

Comments:

Reviewed by		Date	

12.0 DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP No: -" Handling Of Deviations" Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

Reviewed by		Date	

13.0 REFERENCES

The Principle Reference is the following

- Master Validation Plan.
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol 2 – Good Manufacturing Practices and Inspection.

The following references are used to give 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*, General. 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.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- SOP No -"Handling of Deviations".
- SOP No -"Change Control Procedure".

14.0 LIST OF ANNEXURES

Annexure No.	Document Title

15.0 SUMMARY

16.0 POST APPROVALS

The following approvals signify that the OQ is complete and acceptable and that the system is ready for PQ Execution.

PRPARED BY:

Functional area	Name	Signature	Date
Production			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			

AUTHORISED BY:

Functional area	Name	Signature	Date
Head Quality			