

INSTALLATION QUALIFICATION

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| 1.0 | PROTOCOL APPROVAL: |
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Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Auto Coater has been reviewed and approved by the following persons:

| FUNCTION | NAME | DEPARTMENT | SIGNATURE | DATE |
|-------------|------|------------------------|-----------|------|
| PREPARED BY | | QUALITY ASSURANCE | | |
| REVIEWED BY | | PROJECTS / ENGINEERING | | |
| REVIEWED BY | | PRODUCTION | | |
| APPROVED BY | | QUALITY ASSURANCE | | |

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| 2.0 | OVERVIEW: |
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| 2.1 | OBJECTIVE: |
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The objective of developing and executing this protocol is to collect sufficient data pertaining to the Auto Coater and define the installation qualification requirements and acceptance criteria for the Auto Coater. Successful completion of these installation qualification requirements will provide assurance that the Auto Coater was installed as required in the manufacturing area.

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| 2.2 | PURPOSE: |
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The purpose of this protocol is to establish documentary evidence to ensure that the Auto Coater system received matches the Design specification and also to ensure that it is properly and safely installed.

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| 2.3 | SCOPE: |
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This Protocol is applicable to installation of Auto Coater at the tablet manufacturing facility at (Company Name) & the subsequent documentation.

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| 2.4 | RESPONSIBILITY: |
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The following shall be responsible:

- Quality Assurance officer/ Executive - Preparation of protocol
- Projects / Engineering Head – For execution
- Production Head – For execution support
- Quality Assurance Head – For adequacy and final approval

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| 2.5 | EXECUTION TEAM: |
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The satisfactory installation of the Sejong Auto Coater shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Auto Coater is installed satisfactorily.

Execution team is responsible for the execution of installation of Auto Coater
Execution team comprises of:

| DEPARTMENT | DESIGNATION | NAME | SIGNATURE | DATE |
|--------------------------|-------------|------|-----------|------|
| PROJECTS/ ENGINEERING | | | | |
| PRODUCTION | | | | |
| QUALITY ASSURANCE | | | | |

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| 3.0 | ACCEPTANCE CRITERIA: |
| 3.1 | The Auto Coater shall meet the system description given in design qualification. |
| 3.2 | The Auto Coater shall meet with the acceptance criteria mentioned under the topic "Identification of major components" |
| 3.3 | The Auto Coater system shall be operated by PLC. |

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| 4.0 | REVALIDATION CRITERIA: |
| | The Auto Coater has to be revalidated if |
| | <ul style="list-style-type: none"> There are any major changes in system components which affect the performance of the system After major breakdown maintenance is carried out. As per revalidation date and schedule |

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| 5.0 | INSTALLATION QUALIFICATION PROCEDURE: |
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| 5.1 | AUTO COATER (Modal)SYSTEM DESCRIPTION: |
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Process Equipment Description

The purpose of Sejong Auto coating Machine SFC 100FN is to coat tablets of all common sizes and shapes whether it is for film or aqueous coating. The hot air in this equipment will enable a very efficient heat and mass transfer. The hot air flow is controlled by PLC and is programmable to accommodate for various types of tablets and their coating materials.

Complete machine can be divided in following sub sections:

- Inlet System
- Pan
- Spray System
- PLC System
- Cleaning system
- Exhaust System
- Control System

Inlet System: It consists of pre & medium air filters, HEPA filters (Optional), air heating unit and airflow & temperature measuring devices. Inlet air handling unit (Inverter control) receives air from the environment and processes the inlet air and controls the inlet airflow.

Pan: It consists of the semi-perforated fully enclosed pan which contains 8 ducts that engages with the incoming air and the outgoing air through arc shaped inlet duct from the heat exchanger and outlet duct that goes to the exhaust. At any point of time two circular cross sectional area of the pan engages with the hot air inlet and outlet.

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Spray System. It consists of peristaltic pump in case of film coating. This pump is selected based on the viscosity of the solution that has to be coated. This pump is eventually connected to the tubing that leads to high-pressure low volume guns. The angle of spray and the flow rate are externally controllable.

A programmable logic controller (PLC) will execute the direction of the sequence of operation. The PLC of OMRON (or equivalent) is used for this purpose.

5.2 PLC Description

The main function of a PLC is to translate the instructions into the digital or analog codes needed to operate the device or machine.

PLC collects data from field instrumentation & display the information on the operator station. The instruments are connected to the system equipment and piping. The collected data will be utilised by the PLC for process control.

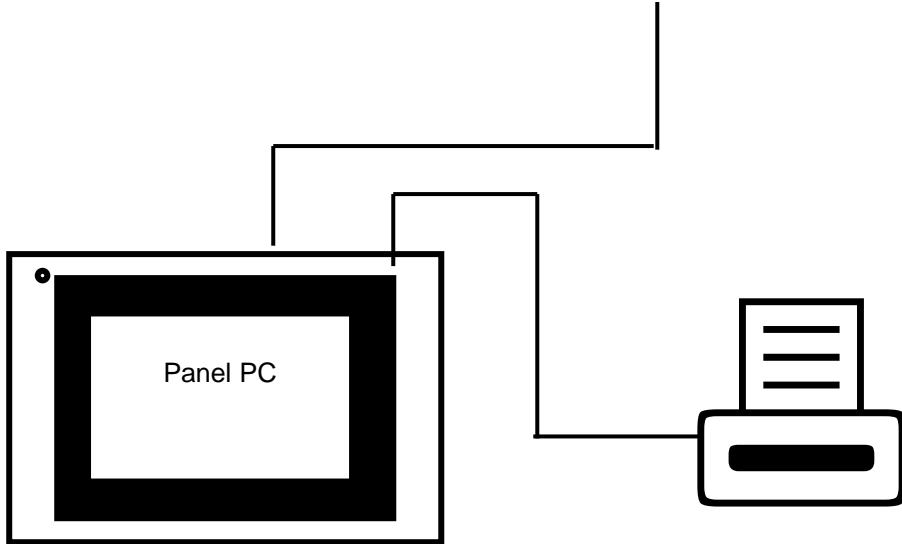
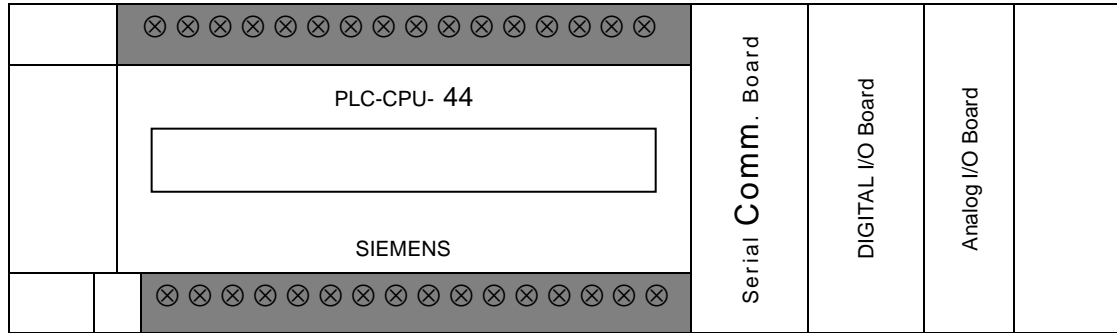
The user interface, based in an industrial type HMI, will assist the operator to supervise and control the process. Based on the displayed information the operator, by means of the user interface, can provide commands to the PLC.

The PLC then executes the operator instructions. An OMRON PLC CQM1H-CPU44 has been chosen as the Central Processing Unit (CPU). There are six inner boards available, which are mounted in Slot 1 or Slot 2 of a COMQ1H-CPU44. The protocol macros are made on the CX – Protocol Support Software and then recorded in the Serial Communication Board, where they can be executed any time using the PMCR instruction in the CPU unit's ladder diagram.

The PLC system layout for the coating machine automation is as shown below:

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Operating Terminal

HP Laserjet/Inkjet Printer

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| 5.2 | INSTRUCTION FOR FILLING THE CHECKLIST |
| 5.2.1 | In case of the compliance of the test use the word 'Complies' otherwise use 'Does not comply' to indicate non-compliance. |
| 5.2.2 | For identification of the components of the equipment and utilities use the word "yes" to show its presence and use 'No' to indicate the absence of the identity |
| 5.2.3 | Give the detailed information in the summary and conclusion part of the Installation Qualification report. |
| 5.2.4 | Whichever column is blank or not used 'NA' shall be used. |

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| 5.3 | INSTALLATION CHECKLIST: |
| | Installation checklist is as follows: |

| Sr.NO. | STATEMENT | YES / NO | CHECKED BY (SIGN) | DATE |
|--------|--|----------|-------------------|------|
| 1. | Verify that the "As Built" drawing is complete and represents the design concept. | | | |
| 2. | Verify that major components are securely anchored and shock proof. | | | |
| 3. | Verify that there is no observable physical damage. | | | |
| 4. | Verify that there is sufficient room provided for servicing. | | | |
| 5. | Verify that all piping and electrical connections are done according to the drawings. | | | |
| 6. | All access ports are examined and cleared of any debris. | | | |
| 7. | Safe electrical connections. | | | |
| 8. | Sufficient room provided for maintenance. | | | |
| 9. | Equipment identification nameplate visible. | | | |
| 10. | Units installed on foundation are secure in place as per manufacturer's recommendations. | | | |

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| 5.4 IDENTIFICATION OF MAJOR COMPONENTS: |
| Describe each critical component and check them and fill the inspection checklist. |

| System Components | Design Specification | | Complies / Does Not Comply | Checked By (Sign) | Date |
|--------------------------|--------------------------|------------------|----------------------------|-------------------|------|
| 1. Equipment Description | Model | Modal Name | | | |
| | Output Capacity | 120 - 150 Kg | | | |
| | Power of Main motor | 3.7KW | | | |
| | Hot water Pressure | 3 Kg/cm sq. | | | |
| | Volume of Heating | 42000 K Cal | | | |
| 2. Pan | Pan diameter | 1300mm | | | |
| | Material | SS 316L | | | |
| | Spray Sliding Cylinder | SS 304 | | | |
| | Rabbit Ear Baffles | 7 Nos. | | | |
| | Pan Motor | 3 HP | | | |
| | Pan speed | 1 - 12 RPM | | | |
| 3. Solution Tank | Capacity | 100 L | | | |
| | Material of construction | SS316L | | | |
| | Manufacturing Design | Casters mounted. | | | |
| 4. Air Device Rating | Main Air Regulator | 0~10 Kg/cm sq. | | | |
| | Atom Air Regulator | 0~10 Kg/cm sq. | | | |
| | Spray Gun Air Regulator | 0~10 Kg/cm sq. | | | |
| | Air Pump Regulator | 0~10 Kg/cm sq. | | | |
| | Main Pressure Gauge | 0~10 Kg/cm sq. | | | |
| | Air Flow Meter | 0~500 Lit/min. | | | |
| | Manometer | 0~500 mm Aq | | | |
| 5. Pump | Manufacturer | XYZ | | | |

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| System Components | Design Specification | | Complies / Does Not Comply | Checked By (Sign) | Date |
|---------------------------------|--|---|----------------------------|-------------------|------|
| | Model | 504S/RL | | | |
| | RPM | Max220 | | | |
| | Shaft Torque | 2.2 Nm | | | |
| 6. Other Components | Touch Screen | XYZ | | | |
| | Proximity switches | Autonics Corporation | | | |
| | Flowmeter | Dwyer | | | |
| | Magnehelic Differential pressure gauge | Dwyer | | | |
| | Solenoid Valve | TPC Pneumatics | | | |
| | VFD | Mitsubishi Electric | | | |
| 7. Spray Gun | Manufacturer | XYZ | | | |
| | Model | 1AV-HVLP | | | |
| 8. Exhaust Blower Air Fan Motor | Manufacturer | XYZ | | | |
| | Speed Controller | XYZ VFC | | | |
| | Filter | Polyester filter bag with auto shaking function | | | |
| 9. Operating Control Panel | PLC Make | XYZ | | | |
| | PLC Model | Sysmac CJ1G | | | |
| | PLC CPU | CPU 44 | | | |

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| 5.5 | Verification of Material of construction: |
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| Sr. No. | Name of components | Material of construction | Method of verification | Verified by (Sign & Date) |
|---------|-------------------------------------|----------------------------|------------------------|---------------------------|
| 1 | Rotary Inlet Outlet Valve | SS 41 | | |
| 2 | Outside Door | SS304 | | |
| 3 | Outside Cover | SS304 | | |
| 4 | Pan Door | SS316 & Strengthened Glass | | |
| 5 | Auto damper | SS304 | | |
| 6 | Coating Pan | SS316 | | |
| 7 | Film Tank | SS 316 | | |
| 8 | Coating Door | SS 304 | | |
| 9 | Machine Body | Frame: SS41, Cover: SS 304 | | |
| 10 | Liquid Tank Flange | SS304 | | |
| 11 | Tank Top Cover | SS304 | | |
| 12 | Liquid Tank | SS316 | | |
| 13 | Liquid Tank Oil Seal Cover | SS304 | | |
| 14 | Liquid Tank Impeller shaft coupling | SS304 | | |

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| 5.6 | IDENTIFICATION OF SUPPORTING UTILITIES: |
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| UTILITY | PROPERLY IDENTIFIED & CONNECTED (YES/NO) | CHECKED BY (SIGN) | DATE |
|--|--|-------------------|------|
| 1) Electricity: 3 Phase, 415Volts, 50Hz | | | |
| 2) Compressed air 6 kg/cm ² 12 mm, 500 L/min | | | |
| 3) Hot water 65000 Kcal/Hr, 2Kg/cm ² | | | |

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| 5.7 | IDENTIFICATION OF SAFETY FEATURES: | | |
| | Identify and record the safety features (if any) and their function in following tables: | | |
| Safety Features Description | Function | Identified By (Sign) | Date |
| Earthing | To avoid electrical shocks due to leakage current. | | |
| Alarm Message | | | |
| 1. Purging Air Pressure Low | If the air pressure drops below the minimum set level, then this alarm will trip the machine. | | |
| 2. Machine Stoppage | If emergency stop is operated the alarm will generate | | |
| 3. Main Motor Overload | If the Sharft motor is overload the alarm will generate and trip the process | | |

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| 5.8 | IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP) |
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The following Standard Operating Procedures were identified as important for effective performance of Auto Coater

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| 1 | Operation and cleaning of Auto Coater |
| 2 | Preventive maintenance of Auto Coater |

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| 5.9 | TEST INSTRUMENT DETAILS |
| | <p>Instrument/Equipment required:</p> <ol style="list-style-type: none"> 1. Tacho Meter 2. Anemometer 3. Temperature sensor 4. Pressure Gauge 5. Photometer |

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| 5.10 | IDENTIFICATION OF COMPONENT TO BE CALIBRATED |
| | <p>In the Auto Coater, following are the components, which needs calibration. Following are the components:</p> <ol style="list-style-type: none"> 1. Pressure Measurement (Purging Air) 2. Temperature Measurement 3. R.P.M. |

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| 5.11 | VERIFICATION OF DRAWING AND DOCUMENTS: |
| | Following documents are reviewed and attached as listed below: |

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| 5.12 | ABBREVIATIONS |
| | Following Abbreviations are used in the installation qualification protocol of Air handling unit |
| | MOC: Material of construction RPM: Rotation per minute Nm: Neuton meter PLC: Programming Logic Controller ACT : Auto Coater |

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| 5.13 | DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S) |
| Following deficiency was identified and corrective actions taken in consultation with the validation team. | |

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| Description of deficiency: |
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| Corrective action(s) taken: |
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Reviewed By:
 Date
5.14 Annexure(s):

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| Sr.No. | Annexure No. | Title of Annexure |
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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

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All the IQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of IQ shall be used to draw conclusion for approval of installation qualification report.

6.1 SUMMARY**6.2 CONCLUSION****6.3 FINAL REPORT APPROVAL**

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It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of Auto Coater have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

| NAME | DESIGNATION | DEPARTMENT | SIGNATURE | DATE |
|------|-------------|---------------------------|-----------|------|
| | | PROJECTS / ENGINEERING | | |
| | | PRODUCTION | | |
| | | QUALITY ASSURANCE | | |