



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL  
CUM REPORT  
FOR  
LOEDIGE COATER**

**PROTOCOL No.:**

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**1.0 PROTOCOL APPROVAL:**

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 Bectochem Loedige Coater has been reviewed and approved by the following persons:

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Bectochem Loedige Coater and define the installation qualification requirements and acceptance criteria for the Bectochem Loedige Coater. Successful completion of these installation qualification requirements will provide assurance that the Becoater was installed as required in the manufacturing area.

The Qualification of Bectochem Loedige Coater performed in view of Coating area manufacturing facility.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Bectochem Loedige Coater received matches the Design specification and also to ensure that it is properly and safely installed.

**2.3 SCOPE:**

This Protocol is applicable to installation of Bectochem Loedige Coater in coating of the manufacturing facility.

**2.4 RESPONSIBILITY:**

In accordance with protocol, following functions shall be responsible for the qualification of system.

**Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:**

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons



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- The production operator / supervisor shall carry out the cleaning and operation of machine.

**Head – Production/ Engineering:**

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

**Head – Operation and Quality Assurance:**

- Review and approval of protocol, the completed qualification data package, and the final report.





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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The Bectochem Loedige Coater shall meet the system description given in design qualification.
- 3.2 The Bectochem Loedige Coater shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 The Bectochem Loedige Coater system shall be operated by PLC.
- 3.4 All material of constructions of the contact parts to be checked as per the specifications.

**4.0 REQUALIFICATION CRITERIA:**

The machine shall be requalified if

- 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:**

**5.1 SYSTEM DESCRIPTION:**

1	Equipment Name	:	Bectochem Loedige Coater
2	Supplier/Manufacturer	:	Bectochem Loedige process Technology Pvt.Ltd.
3	Model	:	GMP
4	Capacity	:	Maximum- 607 Kg, Minimum- 137 Kg
5	Pan Volume	:	610 liter.
6	Spray Rate	:	450gm/min
7	Location	:	Coating area I

**5.1.1 Brief process description:**

The Bectochem Loedige Coater is an automatic coating system for under taking efficient coating of tablet in batches. This optimized system enable repeatable & versatile. Implementation of most types of coating including aqueous & organic film coating

- Conventional film coating.
- Functional film coating.
- Enteric / sustained releases, engineered deliveries
- High uniformity coating.

In a typical batch pre determined quantity of tablet cores (ascertained by physical characteristic, density, tumbling of tablets & nature of coating to be applied with in given pan) are loaded into perforated pan through front opening of pan the tablet cores are first pre warmed by blowing commensurate quantities of clarified drying air through the bed.

The tablets are tumbled and mixed with the aid of baffles in the rotating pan. The film forming polymers are sprayed upon the cores by air-atomized spray guns. The spray is delivered concurrently with the drying air for effecting rapid impingement, coalescing & formation of film.

The automation & controls spray guns, peristaltic pump system as per validated sequence, precisely maintain coating conditions, for yielding defined results. Dehumidification systems facilitate enhanced performance and reproducibility round the year.



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**5.1.2 MACHINE DESCRIPTION**

Bectochem Loedige Coater is automated tablet coating system for efficient film / sugar coating of tablets with cGMP compliance in closed condition. The main pan unit consists of cylindrical perforated pan with conical ends in SS walled enclosure. Tablets to be coated are charged into the coating pan. During film coating process, coating fluids are sprayed (film coating) through gun header (multiple air born spray gun (s) mounted with in the pan from front door.)

Alternatively the sugar syrup may be administered through the front opening with the dosing assembly. A peristaltic pump is employed for precise delivery of fluid. The tablet bed is gently and efficiently mixed during pan rotation with the aid of mixing baffles attached internally, with in pan. The coated tablet are dried with heated, air supplied from an inlet Air handling system - which contains pre filters 10 micron, Hot water coils, 3 micron and 0.3 micron filters.

As a result, applied coating is dehumidified and dried with non-contaminated, dust free and optimized volumes of air for producing uniformly coated tablet.

**Bectochem Loedige Coater comprises of following components: -**

1. Perforated cylindrical Pan
2. Drive (motor, gear box, Sprocket wheel, and chain)
3. Supply blower with AHU
4. Steam heater.
5. Supply & Exhaust duct system
6. Spray system with peristaltic pump
7. Operating panel
8. Main control panel
9. WIP system
10. Solution tank assembly
11. Baffles





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**5.2 INSTRUCTION FOR FILLING THE CHECKLIST:**

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



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**5.3 INSTALLATION CHECKLIST:**

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Physically		
2	Verify that there is no observable physical damage	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe	Physically		
6	Verify that the equipment is properly earthed	Physically		
7	Verify that utility line is properly connected	Physically		
8	Verify the proper leveling of equipment	Physically		
9	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
10	Equipment/system identification no. Is visible	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

<b>System Components</b>	<b>Design Specification</b>		<b>Method Of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
<b>Main coating Pan assembly</b>					
Perforated pan shell	Make	BLPTPL	Visually		
	Size	1338 mm	Physically by measuring tape		
Bottom plate	Should be available.		Visually		
Retractable arm	Should be available.		Physically		
Gear Box	Make	shanthi	Physically		
	Model	To be recorded	Physically/ Technical Specification		
	Ratio	60:1	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
Motor For Pan	Make	Hindustan Motor	Physically		
	Spec.	3 Phase, FLP motor, Foot Mtd., 10HP, 1450 RPM, 50 Hz, 415V.	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
VFD for motor pan	Make	ABB	Physically		
	Model	To be recorded	Physically		
Light Fixture with lamp.	Make	STD	Physically/ Technical Specification		
	Spec.	LED Light	Physically		
Square Gasket for Door	MOC	Food Grade Silicone white	Physically/ Technical Specification		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method Of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
<b>Spray Assembly</b>					
Spray gun	Make	Spraying System	Physically		
	Size	SS316L, 1.2 mm Orifice	Physically/ Technical Specification		
	Qty.	04 Nos.	Physically		
Peristaltic Pump	Make	Flowtech	Physically		
	Type	FLP, Single head Single Drive	Physically/ Technical Specification		
	Model	FP-03	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Peristaltic Pump Motor	Make	HMM	Physically		
	Spec.	3 Ph, 0.18 Kw,0.25 HP	Physically		
	Sr. No.	To be recorded	Physically		
<b>Solution Tank</b>					
Solution Tank	Make	BLPTPL	Physically/ Technical Specification		
	Capacity	100 Ltr.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Pneumatic Motor	Make	PTM	Physically		
	Sr. No.	To be recorded	Physically		
Silicon tube for Liquid inlet	Make	Jayanti Elastomer Processor	Physically		
	Spec.	Food Grade Silicon White , 11 mm OD X8 mm ID	Physically/ Technical Specification		
<b>WIP System</b>					
Multistage	Make	CNP	Physically		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method Of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
Centrifugal Pump	Spec.	FLP, 3 HP , 2880 RPM, 415V, 50HZ.	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
Spray Ball for Inlet & Exhaust Duct Wash	Make	Spraying Systems (India) Pvt. Ltd.	Physically		
	MODEL	EA2E.220.M1.XC	Physically		
	Size	3/8" BSP (M)	Physically/ Technical Specification		
Spray Ball for Shoe Wash	Make	Spraying Systems (India) Pvt. Ltd.	Physically/ Technical Specification		
	MODEL	EA2E.220.M1.XC	Physically		
	Size	3/8" BSP (M)	Physically/ Technical Specification		
Spray Nozzle for drum inner Wash	Make	Spraying Systems (India) Pvt. Ltd.	Physically/ Technical Specification		
	MODEL	EA2E.220.M1.XC	Physically/ Technical Specification		
	Size	3/8" BSP (M)	Physically/ Technical Specification		
Jet Gun for External wash	Make	BLPTPL	Physically		
	Qty.	01	Physically		
Manual Butterfly Valve for duct wash	Make	Valfit	Physically/ Technical Specification		
	Spec.	1" with handle	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Qty				
	Qty	02 Nos.	Physically		
Manual Butterfly Valve for drum inner	Make	Valfit	Physically/ Technical Specification		
	Spec.	1'' with handle	Physically/ Technical Specification		
	Qty	01 Nos.	Physically		
Manual Butterfly Valve for Jet gun for external wash	Make	Valfit	Physically/ Technical Specification		
	Spec.	1'' with handle	Physically/ Technical Specification		
	Qty	01 Nos.	Physically		
Manual Butterfly Valve for Drain & Over flow	Make	Valfit	Physically/ Technical Specification		
	Spec.	2'' with handle	Physically/ Technical Specification		
	Qty	02 Nos.	Physically		
Manual Butterfly Valve for inner wash inlet & inner Tray	Make	Valfit	Physically/ Technical Specification		
	Spec.	2'' with handle	Physically/ Technical Specification		
	Qty	01 Nos.	Physically		
Manual Butterfly Valve at pump inlet/outlet	Make	Valfit	Physically/ Technical Specification		
	Spec.	1½'' with handle	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Qty				
	Qty	02 Nos.	Physically		
Manual Butterfly Valve wash inner & Recirculation	Make	Valfit	Physically/ Technical Specification		
	Spec.	1½''- One Nos 2''- Two Nos.	Physically/ Technical Specification		
	Qty	03 Nos.	Physically		
<b>Air Handling Unit (AHU)</b>					
Air Handling Unit	Make	Damcon	Physically/ Technical Specification		
	Spec.	Modular Sandwiched Fabricated panel	Physically		
	Capacity	5000 CFM	Physically/ Technical Specification		
Inlet Blower	Make	Hari Udyog	Physically		
	Spec.	5000 CFM, 20''WG, Casing-SS304, Impeller-SS304, MOC of stand-SS304.	Physically/ Technical Specification		
	Type	Backward Curve Direct Drive With Impeller	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Make	Description			
Inlet Blower Motor Inlet Blower Motor	Make	Crompton	Visually on name plate / Technical specification		
	Description	3 Ph., Non FLP, 30 HP, 415, 50 Hz, 2940 RPM.			
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
VFD for Inlet Blower Motor	Make	ABB	Physically		
	Spec.	ACS550-01-045A-4	Physically		
Filters	Make	Neftil	Physically		
	10 Micron (pre Filter)				
	Size	24" X 24" X 6" 24" X 12" X 6"	Physically/ Technical Specification		
	Qty	02 + 02 Nos.	Physically		
	03 Micron Filter				
	Size	24" X24" X12" 24" X12" X12"	Physically/ Technical Specification		
	Qty	02 + 02Nos.	Physically		
	0.3 Micron Filter (HEPA)				
	Size	24"X 24"X12" 24"X 12"X12"	Physically/ Technical Specification		





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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Qty				
Steam Coil (Steam Heater)	Qty	02 + 02Nos.	Physically		
	Make	Apollo	Physically/ Technical Specification		
	MOC	SS 304 tube with Aluminium fins	Physically/ Technical Specification		
	Qty	1 Nos.	Physically		
Chilling coil	Make	Apollo	Physically/ Technical Specification		
	MOC	Copper tube & Aluminium fins	Physically/ Technical Specification		
Globe Valve on steam inlet line	Make	Bond	Physically		
	Size	40 NB	Physically/ Technical Specification		
Glove Valve on steam outlet line	Make	Bond	Physically		
	Size	25 NB	Physically/ Technical Specification		
PID control Valve on steam inlet line	Make	Dembla	Physically		
	Size	40 NB	Physically/ Technical Specification		
Safety Valve on steam inlet line	Make	Bond	Physically		
	Size	15 NB	Physically/ Technical Specification		
Solenoid valve on steam outlet	Make	Spirax	Physically		
	Size	25 NB	Physically/ Technical Specification		
Steam Trap on steam outlet	Make	Spirax	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Size	25 NB	Physically/ Technical Specification		
Gate Valve on chilling Coil inlet	Make	Decent	Physically		
	Size	50 NB	Physically/ Technical Specification		
Three way valve on chilling line with electrical Actuator	Make	Johnson	Physically		
	Spec.	M9109-GGA4, 40NB	Physically/ Technical Specification		
Safety Valve on Chilling inlet	Make	STD	Physically/ Technical Specification		
	Size	15 NB			
Solenoid valve on Chilling outlet	Make	Avcon	Physically		
	Size	50 NB	Physically/ Technical Specification		
Inlet Duct	Spec.	200 I/D	Physically/ Technical Specification		
	MOC.	SS 304			
Electric Actuated Plate Damper With Electric Actuator at Inlet Duct	Make	Johnson	Physically		
	Model	M-9116	Physically		
Exhaust Blower	Make	Standard	Physically		
	Spec.	5500 CFM, 24" WG, MOC of Casing-MS, Impeller-MS	Physically/ Technical Specification		
Exhaust Blower motor	Make	HMM	Physically		
	Spec.	3 Phase, 7.5 HP, 415 V, 50Hz, 2905 RPM, FR. Size-200L, FLP.	Physically/ Technical Specification		



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	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
VFD for Exhaust Blower motor	Make	ABB	Physically		
	Spec.	7.5 HP, ACS550-01-072A-4	Physically/ Technical Specification		
Electric actuated plate damper with electric actuator at exhaust duct.	MOC	304			
	Make	Johnson			
	Model No.	M-9116-GGA-2			
<b>Wet Scrubber</b>					
Wet Scrubber	Make	BLPTPL	Physically/ Technical Specification		
	Type	Venturi	Physically		
Wet Scrubber Pump with motor	Make	Crompton	Physically		
	Spec.	2830 RPM, 3phase, 415 V, 50Hz	Physically/ Technical Specification		
	Type	DMB10DG	Physically/ Technical Specification		
	Sr.No	To be recorded	Physically		
<b>Control And Automation / Instruments / Measuring Devices</b>					
Main control Panel	Make	BLPT	Physically/ Technical Specification		
	M.O.C	Ms powder coated	Physically		
	Qty.	01	Physically		
HMI	Make	Mitsubishi	Physically		
	Model	E-1101	Physically		
	Qty.	01	Physically		
PLC	Make	Mitsubishi	Physically		
	Qty.	01	Physically		



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	Model	FX3GE40M	Physically		
Input module	Make	Mitsubishi	Physically		
	Model	FX2N-8AD	Physically		
	Qty.	01	Physically		
Output module	Make	Mitsubishi	Physically		
	Model	FX2N-4DA, FX2N-4AD	Physically		
	Qty.	02	Physically		
PT 100 Sensor	Make	AAVAD	Physically		
	Range	0 to 200 <sup>0</sup> C	Physically/ Technical Specification		
	Qty.	(Inlet Duct 1 no) (Exhaust Duct 1 no)	Physically		
Differential Pressure Gauge across Drum	Make	Dwyer	Physically		
	Range	0 to 250 mm of WC	Physically		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
Differential Pressure transmitter across Drum	Make	Dwyer	Visually		
	Range	0-250mm of WC	Visually From name plate/ technical specification.		
Differential Pressure transmitter across HEPA filter.	Make	Dwyer	Visually		
	Range	0-20 inches	Visually From name plate/ technical specification.		
Pressure gauge at steam line	BAUMER	0-10 KG/CM <sup>2</sup>	Visually		
Pressre gauge at chilling line	BAUMER	0-10 KG/CM <sup>2</sup>	Visually		
Differential	Make	Dwyer	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Pressure Gauge across Primary filter	Range	0 to 150 mm WC	Physically		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
Differential Pressure Gauge across Secondary filter	Make	Dwyer	Physically		
	Range	0 to 150 mm WC	Physically		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
	Spec.	0-10 Kg/Cm <sup>2</sup> , 1/2" BSP	Physically		
Velocity Transmitter at Inlet	Make	Dwyer	Physically		
	Model	641-6	Physically		
	Range	0-75 MPS	Physically		
RH sensor at inlet duct	Make	Dwyer	Physically		
	Model	657C-1	Physically		
	Range	0-100% RH	Physically		
Pressure Switches at main air supply	Make	Danfoss	Physically		
	Type	RT- 116	Physically		
	Range	0-10 Kg/Cm <sup>2</sup>	Physically		
Pressure Switches at atomizing air Supply	Make	Danfoss	Physically		
	Type	RT- 116	Physically		
	Range	0-10 Kg/Cm <sup>2</sup>	Physically		
Pressure Regulator for Stirrer	Make	Festo	Physically		
	Spec.	LR-1/4-D-MINI	Physically		
	Qty.	01	Physically		
Main Air Filter + Regulator	Make	Festo	Physically		
	Spec.	LFR-1/2-D-MIDI	Physically		
	Qty.	01	Physically		
Round Air Regulator	Make	Festo	Physically		
	Spec.	LR-D-MIDI-ED43	Physically		
	Qty.	01	Physically		
Flat Air Regulator	Make	Festo	Physically		
	Spec.	LR-3/8-D-MINI	Physically		
	Qty.	01	Physically		
Plunger Air	Make	Festo	Physically		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method Of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
Regulator	Spec.	LR-1/4-D-MINI	Physically		
	Qty.	01	Physically		

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**5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:**

Name of Components	Material Of Construction	Method Of Verification	Observation	Verified By Sign/Date
Perforated pan	SS 316L	By Molybdenum Kit/ Test Certificate		
Cylinder Drum	SS 316L	By Molybdenum Kit/ Test Certificate		
Baffle	SS 316L	By Molybdenum Kit/ Test Certificate		
Solution Tank	SS 316L	By Molybdenum Kit/ Test Certificate		
Agitator	SS 316L	By Molybdenum Kit/ Test Certificate		
Top Lid	SS 316L	By Molybdenum Kit/ Test Certificate		
Nozzle, Cap, Needle	SS 316L	By Molybdenum Kit/ Test Certificate		
Damper	SS 304	By Molybdenum Kit/ Test Certificate		
Main Unit	SS 304/MS Cladded	By Molybdenum Kit/ Test Certificate		
Operating Panel	SS 304	By Molybdenum Kit/ Test Certificate		
Tubing	Silicone	Test Certificate		
Spraying Arm	SS 304	By Molybdenum Kit/ Test Certificate		
Ductings Interconnecting	SS 304 / MS	By Molybdenum Kit/ Test Certificate		
Gasket	Silicone	Test Certificate		
Filter Frame	AL	Physically		
Filter Casing	AL	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 IDENTIFICATION OF SUPPORTING UTILITIES:**

S.No.	Utility	Method of Verification	Observation	Checked By Sign/Date
1.	<b>Electricity:</b> 3 phase, 415V, 50Hz supply with neutral and proper earthing	Physically with clamp meter		
2.	<b>Compressed air</b> 6 Kg/Cm <sup>2</sup>	Physically with pressure Gauge		
3.	<b>Chilled water supply</b>	3kg/cm <sup>2</sup>		
4.	<b>Steam consumption</b>	3.5 kg/cm <sup>2</sup>		

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.7 IDENTIFICATION OF SAFETY FEATURES:**

Identify and record the safety/interlocking features (if any) and their function in following tables:

<b>Safety Features Description</b>	<b>Location/Identification</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Identified By Sign/Date</b>
Earthing	Equipment connected with earthing strip	Physically		
Emergency	Emergency switch provided to stop machine	Physically		
Pan drive motor trip	MCB provided on control panel and inter link with with HMI	Physically		
Inlet air blower motor trip	MCB provided on control panel and inter link with with HMI	Physically		
Exhaust air blower motor trip	MCB provided on control panel and inter link with with HMI	Physically		
WIP Pump Trip	MCB provided on control panel and inter link with with HMI	Physically		
Dosing Pump Tripped	MCB provided on control panel and inter link with with HMI	Physically		
High inlet temp.	RTD sensor provided at inlet	Physically		
High exhaust temp.	RTD sensor provided at outlet	Physically		
Low exhaust temp.	RTD sensor provided at outlet	Physically		
Inlet Air Blower (RTD) Faulty	RTD sensor interlinked with HMI	Physically		
Incoming air pressure Low	Pressure switch provided to sense Incoming air pressure	Physically		
Atomization air pressure low	Pressure switch provided to sense Atomization air pressure	Physically		
Process over	Timer provide in HMI to set and auto stop coater	Physically		



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<b>Safety Features Description</b>	<b>Location/Identification</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Identified By Sign/Date</b>
Electrical parts	All electrical parts are covered and guarded	Visually		
Electrical safety	Overload relays and fuses are incorporated at all necessary locations in circuit.	Visually		

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):**

The following Standard Operating Procedures were identified as important for effective performance of Bectochem Loedige Coater operation.

S.No.	SOP Title	Verified By Sign/ Date

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.11 ABBREVIATIONS**

Following Abbreviations are used in the installation qualification protocol of Bectochem Loedige Coater

MOC: Material of construction

RPM: Rotation per minute

HMI: Human machine interface

PLC: Programming Logic Controller

ATC: Autocoater

MCB: Miniature circuit breaker

DP: Differential pressure

RTD: Resistant temperature detector

WIP: wash in place

FLP: flame proof

SS : Stainless Steel

HEPA: High efficiency particulate air



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**5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

**Description of deficiency:**

**Corrective action(s) taken:**

**Deviation accepted by  
(Sign/Date)**

**Deviation Approved by  
(Sign/Date)**







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**6.0 INSTALLATION QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**6.3 FINAL REPORT APPROVAL:**

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. All amendments and discrepancies are documented, approved and attached to this protocol. If applicable, signature in the block below indicate that all items in this qualification report of Bectochem Loedige Coater have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After successful installation qualification of the Bectochem Loedige Coater the equipment can be taken for operational qualification.

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		