PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	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 Becoater has been reviewed and approved by the following persons:

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

2.0 OVERVIEW:

2.1 OBJECTIVE:

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

The Qualification of Becoater 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 Becoater system 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 Becoater 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

- 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.

2.5 EXECUTION TEAM:

The satisfactory installation of the Becoater shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Becoater is installed satisfactorily.

Execution team is responsible for the execution of installation of Becoater.

Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Becoater shall meet the system description given in design qualification.

3.2 The Becoater shall meet with the acceptance criteria mentioned under the topic "Identification of major components"

3.3 The Becoater 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 re-qualified 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

5.0	INSTALLATION QUALIFICATION PROCEDURE:

5.1	SYSTEM DESCRIPTION:		
1	Equipment Name	:	Becoater
2	Supplier/Manufacturer	:	…….
3	Model	:	60”
4	Sr. No.	:	NA
5	Capacity	:	60” / 1525 mm pan diameter to coat 200 to 300 kgs. (Approx depending on size and shape of tablet
6	Location	:	Coating area

5.1.1 Brief process description:

The Becoater 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 cores are sprayed upon the film forming polymers 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.

5.1.2 MACHINE DESCRIPTION

Becoater 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..

Becoater 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

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.

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	Physically		

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
	connections are properly done and safe			
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: ----------

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

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

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Main coating Pan assembly: Drive Section					
Main Drive Gear Box	Make	Elecon	Physically		
	Type	Horizontal shaft SNU –U,size-8”	Physically		
	Ratio	60:1	Physically		
	Sr. No.		Physically		
	Qty.	01 No.	Physically		
Main Drive Motor	Make	Hindustan Motor	Physically		
	Spec.	3 Phase, FLP motor, Foot Mounted, 7.5 HP, 950 RPM, 50 Hz, 415 V	Physically		
	Sr. No.		Physically		
	Qty.	01 No.	Physically		
VFD for main motor	Make	ABB	Physically		
	Model	ACS-550-01-12A-4	Physically		
Perforated Pan shell	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	SS 316L, 3 Ø x 5mm Triangular Pitch	Physically/ Technical Specification		
	QTY.	01 NO.	Physically		
Pan cone	Make	BLPTPL	Physically/ Technical Specification		
	Qty.	02 Nos	Physically		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Baffle	Make	BLPTPL	Physically/ Technical Specification		
	Type	Blade Type	Physically/ Technical Specification		
	Qty.	06 Nos.	Physically		
Coater Body	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	10SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Bottom tray	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	10SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Pneumatic cylinder for Pan door Open/Close	Make	AirMax	Physically/ Technical Specification		
	Spec.	80 Bore X 1300 Stroke X Piston Rod 32mm	Physically/ Technical Specification		
	Qty.	01 No.	Physically		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Light Fixture with lamp	Make	STD	Physically/ Technical Specification		
	Spec.	FLP	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Bearing Housing with Brg	Make	STD	Physically/ Technical Specification		
	Spec.	M.S., SPH. Roller BRG.22214C	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Acrylic Sheet	Make	STD	Physically/ Technical Specification		
	Spec.	16 THK, Acrylic	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Chain Drive	Make	STD	Physically/ Technical Specification		
	Spec.	Chain – MS Sprockets – CS	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Spray Assembly					

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Spray gun	Make	Spraying Systems	Physically/ Technical Specification		
	Qty.	06 Nos.	Physically		
Peristaltic Pump	Make	Flowtech	Physically/ Technical Specification		
	Spec.	FP 02, FLP, Single Head,Range-1.2 LPM	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
SOLUTION PREPARATION TANK-300 LTRS					
Main Shell	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	12SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Main Bottom Cone	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	12SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Baffle	Make	BLPTPL	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	3Thk	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Top Lid	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	14SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Pneumatic Motor	Make	PTM	Physically/ Technical Specification		
	Spec.	1HP, 2000 RPM, Model-A1050-2000	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Shaft for Impeller	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	25mmdia	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Castor Wheel	Make	Swiss Engg	Physically/ Technical Specification		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	4" X 1 1/2" PU Coated, SS 304 Swivel & Break Type	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Bottom Outlet Ball Valve	Make	Seeco	Physically/ Technical Specification		
	Spec.	SS 316,3/4''with Handle & TC End	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Needle valve at solution return Line	Make	Seeco	Physically/ Technical Specification		
	Spec.	3/8" BSP	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Silicon Tube for Liquid inlet	Make	Acrosil	Test Certificate		
	Spec.	Silicon, 20 MM OD X 16 MM ID	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Silicon Tube for Return Line	Make	Acrosil	Test Certificate		
	Spec.	Silicon, 14 MM OD X 12 MM ID	Physically/ Technical Specification		

 PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Qty.	01 No.	Physically		
WIP System					
Spray Gun (Hand operated)	Make	STD	Physically/ Technical Specification		
	Spec.	Water Saver Gun with 1/2" Hose Connector SS 316	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Spray Ball for inner wash	Make	Atul	Physically/ Technical Specification		
	Spec.	3/4"BSP, SS316	Physically/ Technical Specification		
	Qty.	02 Nos.	Physically		
Spray Nozzle for outer wash	Make	Atul	Physically/ Technical Specification		
	Spec.	3/8" BSP, SS316	Physically/ Technical Specification		
	Qty.	06 Nos.	Physically		
Spray Nozzle for Ducts inner wash	Make	Atul	Physically/ Technical Specification		
	Spec.	3/8" BSP, SS316	Physically/ Technical Specification		
	Qty.	01 No.	Physically		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Niddle valve at WIP Header for compressed air	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	1 /2''BSP	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated butterfly valve on WIP Header for inlet duct wash.TC type	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated butterfly valve on WIP Header for Exhaust duct wash.TC type	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated butterfly valve on WIP Header for Pan inner TC type	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC	Physically/ Technical Specification		
	Qty.	01 No.	Physically		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Manually operated butterfly valve on WIP Header for Pan outer wash TC type	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both sides TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly on WIP Header for Hand Gun Wash TC Type	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly for overflow	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly for Drain	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Manually operated Butterfly valve for re circulation	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly valve for Normal water in	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly on WIP Header inlet	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Manually operated Butterfly for Header Drain	Make	Valfit Engineers	Physically/ Technical Specification		
	Spec.	25mm, SS 304 with Handle both side TC.	Physically/ Technical Specification		
	Qty.	01 No.	Physically		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
WIP Pump with Motor	Make	Grundfos	Physically/ Technical Specification		
	Spec.	KW-1.1,RPM-2830, Modal-CDL-8-3 Head -27mtr, Q=8m^3 /hr	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Inlet Duct Assembly					
Air Handling Unit	Make	Damcon	Physically/ Technical Specification		
	Spec.	Modular Sandwiched fabricated panel. Internally SS304 lined after HEPA. Externally -MS powder coated. Fixing to Aluminium	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Pre Filter (10 micron)	Make	Netfil	Physically/ Technical Specification		
	Spec.	24”X24”X6” 24”x12”x6”	Physically/ Technical Specification		
	Qty.	2+2 Nos.	Physically		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Secondary Filter (3 micron)	Make	Netfil	Physically/ Technical Specification		
	Spec.	24”X24”X12” 24”x12”x12”	Physically/ Technical Specification		
	Qty.	2+2 Nos.	Physically		
HEPA Filter (0.3 micron	Make	Netfil	Physically/ Technical Specification		
	Spec.	24”X24”X12” 24”x12”x12”	Physically/ Technical Specification		
	Qty.	2+2 Nos.	Physically		
Steam Heater	Make	Apollo	Physically/ Technical Specification		
	Spec.	SS304 Tubing & Al Fin	Physically		
	Qty.	01 No.	Physically		
Chilling coil	Make	Apollo	Physically/ Technical Specification		
	Spec.	CU Tubing & Al Fin	Physically		
	Qty.	01 No.	Physically		
Globe Valve on steam inlet line	Make	Spirax	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	40 NB	Physically/ Technical Specification		
	Qty.	03 Nos.	Physically		
Gate Valve on steam outlet line	Make	Spirax	Physically/ Technical Specification		
	Spec.	25 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
PID control Valve on steam inlet line	Make	Dembla	Physically/ Technical Specification		
	Spec.	40 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Safety Valve on steam inlet line	Make	Aira	Physically/ Technical Specification		
	Spec.	25 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Solenoid valve on steam outlet	Make	Aira	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	25 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Steam Trap	Make	Spirax	Physically/ Technical Specification		
	Spec.	25 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Gate Valve on chilling coil inlet	Make	Spirax	Physically/ Technical Specification		
	Spec.	50 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Three way Valve on chilling line with electrical Actuator	Make	Johnson	Physically/ Technical Specification		
	Spec.	50 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Safety Valve on Chilling Inlet	Make	Spirax	Physically/ Technical Specification		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	15 NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Solenoid Valve on Chilling outlet	Make	Aira	Physically/ Technical Specification		
	Spec.	50NB	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Inlet duct	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	SS304,16 SWG, 450 I/D	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Inlet Blower	Make	Hari udyog	Physically/ Technical Specification		
	Spec.	5000 CFM, 8” WG MOC of Casing: SS304, MOC of Impeller:SS304, MOC of Stand: SS 304	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
VFD for Supply Blower Motor	Make	ABB	Physically/ Technical Specification		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	ACS-550-01-23A-4	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Inlet Blower Motor	Make	HMM	Physically/ Technical Specification		
	Spec.	Foot Mounted, Non FLP, 12.5 HP, 2940 RPM Supply: 415 Volts, 3 Phase, 50 Hz	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Inlet Plenum	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	16 SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Actuator for supply duct Damper (Inlet Damper)	Make	Rotex	Physically/ Technical Specification		
	Spec.	ECF-150	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Damper for Supply Duct	Make	BLPTPL	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	450 Ø	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Exhaust Duct Assembly					
Exhaust Duct	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	SS304,16 SWG, 450 I/D	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Exhaust Plenum	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	SS 304,16 SWG	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Exhaust blower	Make	Hari Udyog	Physically/ Technical Specification		
	Spec.	5500 CFM, 12” WG MOC of Casing: MS, MOC of Impeller: MS, MOC of Stand: MS	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Exhaust blower motor	Make	HMM	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	Foot Mounted, non FLP, 15 HP,2950 RPM, Supply: 415 Volts, 3 Phase, 50 Hz	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
VFD for exhaust motor	Make	ABB	Physically/ Technical Specification		
	Spec.	ACS-550-01-23A-4	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Damper for Exhaust Duct	Make	BLPTPL	Physically/ Technical Specification		
	Spec.	450Ø, SS 304	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Actuator for exhaust duct Damper (Exhaust Damper)	Make	Rotex	Physically/ Technical Specification		
	Spec.	ECF-150	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Wet Scrubber	Make	BLPTPL	Physically/ Technical Specification		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	MS	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Wet Scrubber Pump with Motor	Make	Crompton Greaves	Physically/ Technical Specification		
	Spec.	Type-DMB10DG, Head-18-45m,HP-1, RPM-1425,3PH,415V	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Bellow	Make	Acrosil	Physically/ Technical Specification		
	Spec.	Ø250x300 Long, Neoprene Rubber	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Gasket For Ducting	Make	Acrosil	Physically/ Technical Specification		
	Spec.	530 OD X 450 ID X 3 Thk Neoprene Rubber	Physically/ Technical Specification		
	Qty.	04 Nos.	Physically		
Control Panel & Automation					
Main control Panel	Make	BLPTPL	Physically/ Technical Specification		
	M.O.C	Ms powder coated	Physically		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Qty.	01	Physically		
HMI	Make	Mitsubishi	Physically		
	Qty.	01	Physically		
	Model	E-1061.	Physically		
PLC	Make	Mitsubishi	Physically		
	Qty.	01	Physically		
	Model	FX3GE40M	Physically		
Input module	Make	Mitsubishi	Physically		
	Qty.	01	Physically		
	Model	FX2N-8AD	Physically		
Output module	Make	Mitsubishi	Physically		
	Qty.	02	Physically		
	Model	FX2N-4DA	Physically		
Instrument					
PT 100 Sensor	Make	Neptune	Physically/ Technical Specification		
	Spec.	NFLP,1/2”BSP, 200mm Lg with transmitter	Physically/ Technical Specification		
	Qty.	(Exhaust 1 no), (Inlet 1 no), (Bed 1 no)	Physically		
Pressure gauge at (steam line & chilling line)	Make	Waree	Physically/ Technical Specification		
	Spec.	4”dial,0 – 10 kg/cm2 ,1/2” BSP	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Differential Pressure Gauge across cabinet	Make	Dwyer	Physically/ Technical Specification		
	Spec.	0-250 MM WG	Physically/ Technical Specification		
Differential Pressure Gauge Across Primary Filter	Make	Dwyer	Physically/ Technical Specification		
	Spec.	0-5” WG	Physically/ Technical Specification		
Differential Pressure Gauge Across Secondary Filter	Make	Dwyer	Physically/ Technical Specification		
	Spec.	0-5” WG	Physically/ Technical Specification		
Differential Pressure Gauge Across Hepa Filter	Make	Dwyer	Physically/ Technical Specification		
	Spec.	0-5” WG	Physically/ Technical Specification		
PT 100 sensor in exhaust duct	Make	Neptune	Physically/ Technical Specification		
	Spec.	Non FLP, 1/2" BSP, 200mmLg with Transmitter	Physically/ Technical Specification		

PHARMA DEVILS	INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL	PROTOCOL No.:

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
PT 100 sensor at tablet bed	Make	Neptune	Physically/ Technical Specification		
	Spec.	Non FLP, 1/2" BSP, 150mmLg Wire 5meter	Physically/ Technical Specification		
Proxy sensor for RPM sensing	Make	P + F	Physically/ Technical Specification		
	Spec.	M-18 PNP 10-30 DC	Physically/ Technical Specification		
Proxy sensor for Pan Door sensing	Make	P + F	Physically/ Technical Specification		
	Spec.	M-18 PNP 10-30 DC	Physically/ Technical Specification		
Pr Gauge at Steam Line	Make	Waaree	Physically/ Technical Specification		
	Spec.	4" Dial, 0 to 10Kg/Cm², 1/2" BSP	Physically/ Technical Specification		
Pr Gauge at Chilling Line	Make	Waaree	Physically/ Technical Specification		
	Spec.	4" Dial, 0 to 10Kg/Cm², 1/2" BSP	Physically/ Technical Specification		
Velo meter at inlet duct	Make	DWYER	Physically/ Technical Specification		
	Spec.	Model 641-12	Physically/ Technical Specification		
RH sensor	Make	DWYER	Physically/ Technical Specification		

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Spec.	Model 657-C	Physically/ Technical Specification		
Main Air Filter + Regulator	Make	Festo	Physically/ Technical Specification		
	Spec.	LFR-3/8-D-MIDI	Physically/ Technical Specification		
Pressure Regulator for Atomizing Air (Round & Flat)	Make	Festo	Physically/ Technical Specification		
	Spec.	LR-3/4-D-MINI	Physically/ Technical Specification		
Pressure Regulator for Operating Panel Air Purging	Make	Festo	Physically/ Technical Specification		
	Spec.	LR-3/4-D-MINI	Physically/ Technical Specification		
Pressure switch at main air supply	Make	Danfoss	Physically/ Technical Specification		
	Spec.	RT-116	Physically/ Technical Specification		
Pressure switch at atomizing air supply	Make	Danfoss	Physically/ Technical Specification		
	Spec.	RT-110	Physically/ Technical Specification		
Pressure switch for Operating panel air purging	Make	Danfoss	Physically/ Technical Specification		
	Spec.	RT-110	Physically/ Technical Specification		

 **PHARMA DEVILS**	**INSTALLATION QUALIFICATION REPORT FOR COMMINUTING MILL**	**PROTOCOL No.:**

Remark: ----------

Reviewed by (Sign/Date)

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
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		
Discharge Chute	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		
Plenums (In-Let/Exhaust)	SS 304	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's	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		

Finishing is of 320 Grit mirror finish.

Remark: ----------

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method of Verification	Observation	Checked By Sign/Date
1.	**Electricity:** 3 phase, 415V, 50Hz supply with neutral and proper earthing	Physically with clamp meter		
2.	**Compressed air** 5 Bar	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

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

Safety Features Description	Location/Identification	Method Of Verification	Observation	Identified By Sign/Date
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 HMI	Physically		
Pan drive jammed.	Sensor provided with gear box to count pan rotation	Physically		
Inlet air blower motor trip	MCB provided on control panel and inter link with HMI	Physically		
Exhaust air blower motor trip	MCB provided on control panel and inter link with HMI	Physically		
WIP Pump Trip	MCB provided on control panel and inter link with HMI	Physically		
Dosing Pump Tripped	MCB provided on control panel and inter link 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		
Exhaust Air Temp. (RTD) Faulty	RTD sensor interlinked with HMI	Physically		

Bed Temp.Sense RTD Fault.	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		
HEPA Filter Clogged (AHU)	Pressure switch provided and inter linked with HMI	Physically		
AHU Door Open (process terminated)	Limit switch provided and interlinked with HMI	Physically		
Coater door Open (side, front door)	Limit switch provided and interlinked with HMI	Physically		
Needle Solenoid Faulty	Solenoid valve interlinked with HMI	Physically		
Process over	Timer provide in HMI to set and auto stop coater	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Becoater operation

.

S.No.	SOP Title	Verified By Sign/ Date

Remark: ----------

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.11 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

_____

_____

Done By & Date: **Verified By & Date:**

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)

5.13 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Becoater

MOC: Material of construction

RPM: Rotation per minute

HMI: Human machine interface

PLC: Programming Logic Controller

ACT: Becoater

MCB: Miniature circuit breaker

DP: Differential pressure

RTD: Resistant temperature detector

WIP: wash in place

FLP: flame proof

SS : American iron & steel institute

HEPA: High efficiency particulate air filter

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/ Date

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 Becoater have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Becoater the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		