



PHARMA DEVILS

INSTALLATION QUALIFICATION REPORT

FOR

DUST EXTRACTION UNIT

PROTOCOL No.:

**INSTALLATION QUALIFICATION
FOR
DUST EXTRACTION UNIT**

Document Reference: DQ No.: _____

Issue Date: _____



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1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

Functional area	Name	Designation	Signature	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				



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2.0 OBJECTIVE: To ensure that the installed equipment / system conform to the approved design, specification and manufacturers recommendation.

3.0 SCOPE: The scope of this Installation Qualification is for “**DUST EXTRACTION UNIT, Capacity: 180 CFM**” which is installed.

Check Point	To be recorded Manually by User	Checked by (Sign/ Date)
Make/ Model of equipment		
Allocated Equipment code		
Installed in Area Name & code	Area Name : _____ Area Code No: _____	
PO No. & Date		
Challan / Invoice No.		
Installation Qualification	Start date: _____ End date: _____	

4.0 Reason for IQ:

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

- Refurbished premises/equipment
- Purchase of Utility Systems
- Purchase of Process Equipment
- Purchase of Laboratory Equipment
- Bespoke or user configured computer systems
- In-Use Systems that don't have a URS
- Others (Specify)

5.0 Refer attached Manufacturer/Supplier Installation Qualification No. (if applicable):



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Refer attached IQ No.: _____.

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the qualification protocol and verify all the proposed installation parameters of the equipment after/during installation.
Engineering		To verify the utilities, certify components, location and equipment parameters
Health Safety and Environment		To verify and provide the safety requirements of equipment and facility
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document



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7.0 Equipment Description:

Dust Extractor deals with the process to extract the dust from the tablet press during production and keep the compression zone of tablet press clean.

Dust laden air is sucked by a Vortex pump and enters in the filter housing through a suction adaptor, where dust laden air is deflected around filter bag by deflector. Deflected air is sucked by pressure and pass through fine filter bag. The dust particles stuck to the inner wall of the filter housing and outer face of the filter bag. The Dust laden air passes upward through filter bag. The Top of filter cage with filter bag is mounted with highly effective spring action shaking mechanism, operated by a shaking knob on top of the filter housing assembly. On operating the shaking mechanism, the dust deposited on the outer wall of the filter bag is dropped into filter housing. The high level vortex pump is suck the dust laden air through filter bag, then cleaned discharge air in atmosphere after filtered by exhaust filter. Castor wheels are fitted at bottom side of the machine to give complete manoeuvrability.

8.0 Environment: This section gives a brief summary of the layout and physical condition of the proposed site of the equipment. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, door/window locations and dimensions, drain locations, access route from outside, HVAC supply/return grill locations, utility point locations, etc.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Available area	Area (4.6 m Length x 4.5 m Breadth x 4.5 m Height)		
		Area Grade/Class: ISO 8		
		As Built Area Layout attached as attachment No. _____		
		Should be able to accommodate in Blending area		
		Should be installed at the suitable area for ease in cleaning		
2.	Maximum	3280 mm Length (Column to Bin)		



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S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
	Expected size of equipment (approx.)	2030 mm Arm Width		
		2995 mm Height		

9.0 Functional Requirements of Equipment:

9.1 Functionality of the Equipment: The desired functional requirements and how it operates are listed under this section.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
Pillar type Bin Blender:				
1.	Use / Purpose	The equipment should be able for Mixing/ Blending and storage of powders and granules.		
2.	Capacity / Working Capacity	Blending of 600 L capacity bin.		
3.	Model	cGMP Model		
4.	Blending Gear box	Type: Worm and Worm wheel, Hollow shaft		
		Specification: ALM-130, Ratio-80/1		
5.	Blending motor	3 HP		
		RPM: 930 (NOM) $\pm 10\%$		
		Non Flame proof		
		Flange mounted		
		3 Phase		
		415 Volt		
		50 Hz		
6.	Brake for blending motor	Shall be provided		
7.	Hydraulic Power pack unit	Single station		
		Pump: 12 LPM		
		Pressure: 70 bar		



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S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
8.	Hydraulic Power pack motor	3 HP		
		RPM: 1440 (NOM) \pm 10%		
		Non Flame proof		
		Flange mounted		
		3 Phase		
		415 volt		
		50 Hz		
9.	Hydraulic Cylinder	Flange mounted		
		Telescopic cylinder		
10.	Hose pipe	MOC: Rubber		
		Quantity: 2 Nos.		
11.	A.C. Drive	3 HP		
12.	MMI	Model: Panel view -700		
13.	PLC	Model: Micrologix-1400		
IPC Bin:				
1.	Capacity	Volumetric: 260 L		
2.	Dimension	Diameter: 720 mm		
		Height: 1298 mm		
3.	Trolley	Loose trolley for bin movement		
4.	Outlet	Butterfly Valve shall be provided		
5.	Cover	Shall be provided on bin		
6.	Transfer pot	Shall be provided at outlet of bin for transferring bin material into vibratory sifter		
7.	Castor wheel	100 dia x 32 W		
		Plate type, swivel- 2 Nos.		
		Plate type, swivel with brake- 2 Nos		
		Material: Polyurethane		



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S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
Square Bin:				
1.	Gross Capacity	600 L		
2.	Dimension	Square: 1005 mm		
		Height: 1534 mm		
3.	Working capacity	Maximum: 420 Liters (250 kg @ 0.6 BD)		
		Minimum: 210 Liters (125 kg @ 0.6 BD)		
4.	Valve	butterfly valve shall be provided on outlet of bin		
5.	Hand hole	Shall be provided with cover		
6.	Vent	Shall be provided		
7.	Castor wheel	150 dia x 50 W		
		Plate type, swivel with brake Quantity: 02 Nos.		
		Plate type, swivel without brake Quantity: 02 Nos.		
		Material: Polyurethane		

9.2 Instrumentation Requirements: This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. RPM indicator, pressure gauge, flow meter, printer etc.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Pressure gauge for power pack	Shall be provided		

9.3 Data Collection and Reporting: This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts are also to be mentioned, if applicable e.g. temperature, RPM, pressure, etc.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Time	In Minutes/seconds.		
2.	RPM	In Numbers		



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9.4 Recipe Provision / Data Saving / Data Back-up / Data Security: This section specifies the requirements (as applicable) for recipe provision, data saving facility, data back-up facility, data security facilities, etc.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Data security facility	Access should be controlled through password protection.		

9.5 Performance Features: The parameters that are planned to be evaluated during performance qualification and process validation activities are mentioned.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Performance of the machine according to operation.	The machine is intended to be operated regularly: 24 hours, 7 days per week with cleaning in between batch/ product changeover.		
2.	Change over time	A minimum change part to reduce the product change over time is required.		
3.	Cleaning Requirements	Easy accessible for cleaning. Parts which are required for cleaning should be provided with quick fixing arrangement.		



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9.6 Capacity / Speed: The desired capacity/speed with the UOM is specified in this section.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	IPC Bin Capacity	Volumetric: 260 L		
2.	Square Bin capacity	Gross: 600 L		
		Working Capacity: Maximum: 420 Liters (250 kg @ 0.6 BD) Minimum: 210 Liters (125 kg @ 0.6 BD)		
3.	Blender Speed	Final Speed: Max. 10 RPM \pm 2 RPM		
		Variable from 2 to 10 RPM		

9.7 Automation and Safety Features: The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section. e.g. for loading/unloading/material handling/ WIP activities, etc.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Limit Switch	Shall be provided for stopping of bin at blending height		
		Shall be provided for stopping the bin at discharge height		
		Shall be provided for sensing the bin at blending height		
2.	Railing	Shall be provided in front of the machine and interlock through limit switch		
3.	Brake with limit switch	Shall be provided for stopping the blender in vertical position		
4.	Emergency Stop	Shall be provided on operating panel to stop the bin in case of emergency		
5.	Corners of IPC Bin	Shall be rounded		



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9.8 System Boundaries: Nil.

9.9 Material of Construction: Specifications for material of construction of contact parts, non-contact parts, etc. are listed here.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Pillar type Bin Blender	Column: M.S. with SS 304 cladded		
		Arm: M.S. with SS 304 cladded		
		Shaft: M.S.		
		Shaft Flanges: M.S.		
		Operating panel: S.S. 304		
		Control panel: M.S. with powder coated		
		Railing: SS 304		
2.	IPC Bin	Shell: SS 316		
		Cone: SS 316		
		Cover: SS 316		
		Butterfly valve flap: SS 316		
		Trolley: SS 304		



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S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
3.	Square Bin	Shell: SS 316		
		Cone: SS 316		
		Cover: SS 316		
		Butterfly valve flap: SS 316		
4.	Gasket	Silicon/ Neoprene, Non – toxic, food grade.		

9.10 Surface Finish: Specifications for surface finish of contact parts, non-contact parts, etc. are listed here.

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Internal Surface finish (Product contact parts)	IPC Bin and Square Bin: Smooth and Mirror polished inside surface with no welding burrs and crevices. Corners shall be rounded		
2.	Outer Surface finish	Pillar: Dull polished & column inside portion is painted with epoxy paint.		



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9.11 Electrical and Control Equipment Philosophy: A brief detail of the control requirements and whether the equipment are to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	PLC	Both Manual and Auto mode. Touch screen MMI & PLC inclusive of Auto / manual mode		
		MMI with PLC control should indicate: 1. Blending RPM, 2. Auto/ manual mode, 3. M/c ON/Off control		
2.	MMI	On the operating panel for operating the machine and setting the programme in Auto/manual mode.		

9.12 GxP Considerations: The requirements for electronic compliance of the equipment.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Security Levels	Three Level Security should be provided (Operator, Supervisor and Master)		
		Operation Control for operator		
		For password at least 4 characters required to enforce their use		
		When password entry fields are shown on the screen, password entries must be obscured (e.g. "*****").		



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10.0 Expected Documents and Drawings: Requirement of documents (whichever applicable) to be delivered by the manufacturer/ supplier during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

S. No.	Document details	Required (✓ / ✗)
1.	Design Specifications	<input checked="" type="checkbox"/>
2.	Functional Specifications	<input type="checkbox"/>
3.	PLC Alarm/Interlock/Safety/ communication/power failure test procedures	<input checked="" type="checkbox"/>
4.	Piping and Instrumentation Diagram (P&ID)	<input type="checkbox"/>
5.	Instrument Listing	<input checked="" type="checkbox"/>
6.	Control Schematics	<input type="checkbox"/>
7.	Control Panel Assembly Drawings	<input type="checkbox"/>
8.	Machine Assembly Drawings	<input type="checkbox"/>
9.	Bill of Materials	<input type="checkbox"/>
10.	Operator, Maintenance and Service Manuals	<input checked="" type="checkbox"/>
11.	Spare Parts List	<input checked="" type="checkbox"/>
12.	MOC certificates	<input checked="" type="checkbox"/>
13.	Calibration certificates of instruments	<input checked="" type="checkbox"/>
14.	Test certificates of components/test devices	<input type="checkbox"/>
15.	Weld certificates (if any)	<input type="checkbox"/>
16.	'As-built' P&ID	<input type="checkbox"/>
17.	GA drawing	<input checked="" type="checkbox"/>
18.	Isometric drawing (if any)	<input type="checkbox"/>
19.	Electrical drawings	<input checked="" type="checkbox"/>
20.	Component Cut Sheets (optional)	<input type="checkbox"/>



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S. No.	Document details	Required (✓ / ✗)
21.	PLC Program Printouts and Disk File (optional)	<input checked="" type="checkbox"/>
22.	HMI Configuration Printout and Disk File (optional)	<input checked="" type="checkbox"/>
23.	Other (Specify)	<input checked="" type="checkbox"/>

✓ : Received ✗ : Not Received

11.0 Available Utilities:

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Electricity	Electrical supply three Phase		
		Frequency: 50 Hz		
		Voltage: 415 volts		
		Neutral and earthing shall be provided.		

12.0 Maintenance Requirements: Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

S. No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
1.	Maintenance	Easy accessibility for maintenance		
2.	Spare parts	List of spare parts and spare parts should be provided		

13.0 Reference Documents: Nil.



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16.0 Deviations/ Changes (if any):

17.0 Recommendations/ Conclusion :



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18.0 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
REVIEWED BY				
User Dept. Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				