



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
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**Document Reference: DQ No.:** \_\_\_\_\_

**Issue Date:** \_\_\_\_\_



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**CONTENTS**

<b>S.No.</b>	<b>Title of sections</b>	<b>Page No.</b>
1.0	Pre-approval	4
2.0	Objective	5
3.0	Scope	5
4.0	Reason for IQ	5
5.0	Refer attached Manufacturer/Supplier Installation Qualification No. (if applicable)	6
6.0	Responsibility	6
7.0	Equipment Description	7
8.0	Environment	7-8
9.0	Functional Requirements of Equipment	8
9.1	Functionality of the Equipment	8-11
9.2	Instrumentation Requirements	11
9.3	Data Collection and Reporting	11
9.4	Recipe Provision/ Data Saving/ Data Back-up/ Data Security	11
9.5	Performance Features	12
9.6	Capacity / Speed	13
9.7	Automation and Safety Features	13-14
9.8	System Boundaries	14
9.9	Material of Construction	14-15
9.10	Surface Finish	15
9.11	Electrical and Control Equipment Philosophy	15-16
9.12	cGxP Considerations	16
10.0	Expected Documents and Drawings	17-18
11.0	Available Utilities	18
12.0	Maintenance Requirements	18
13.0	Reference Documents	19



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

<b>S.No.</b>	<b>Title of sections</b>	<b>Page No.</b>
14.0	Abbreviations	19
15.0	Attachments	19-20
16.0	Deviations/ Changes	20
17.0	Recommendations/ Conclusion	20
18.0	Post approval	21



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**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.

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



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**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 “**BIN BLENDER (PILLAR TYPE), Capacity: 600 Litres**”.

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)



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

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

Refer attached IQ No.: \_\_\_\_\_.

**6.0 Responsibility: Personnel involved in qualification activity.**

<b>Department</b>	<b>Name</b>	<b>Activity</b>
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



PHARMA DEVILS

INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)

PROTOCOL No.:

**7.0 Equipment Description:**

**Pillar type Blender:** The machine mainly consists of frame, blending mechanism & lifting arrangement. The blender column is fabricated from M.S pipe, M.S plate and clad with SS sheet. The M.S. trolley moves up and down inside the column. For lifting the trolley with bin holding arm, the hydraulic cylinder is fitted on the base plate of column and then connected with the trolley. The hydraulic cylinder is operated by hydraulic power pack unit. The blending movement is achieved with the help of geared unit. In blending mechanism bearing housing is fitted inside the bearing housing sleeve, which is welded to trolley. The drive shaft is assembled with bearing housing. The flange is welded on the one end of the drive shaft for bolting the bin holding arm. The blender arm is bolted with drive shaft flange. The gear box and motor is mounted on the other end of the drive shaft. The blender speed can be varied from 2 to 10 RPM. The A.C. drive is used for varying speed of blender.

**IPC Bin:** The bin shall be fabricated from SS 316 sheet having conical bottom with butterfly valve for easy transferring the material into the machine. The inner and outer surface of the bin shall be mirror polished. For movement of the bin a loose circular trolley shall be provided with polyurethane wheels.

**Square Bin:** The bin shall be fabricated from SS 316 sheet having square shell welded with conical bottom and top flat. The butterfly valve is provided at the bottom of the cone for easy transferring the material into the container. On the top of bin Hand hole is provided with easy opening of the lid for charging the materials. The square frame which made of square pipe is welded on the bin shell for holding into the arm of the pillar bin blender for blending. For placing the bin into the elevator arm, 2 nos. pipes are welded on square frame of the bin. The inner are mirror polished and outer surfaces are dull polished. For the mobility of the bin, trolley is provided which is fabricated from pipes and movement of trolley polyurethane castor wheels is provided.

**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.



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

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 Expected size of equipment (approx.)	3280 mm Length (Column to Bin)		
		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
<b>Pillar type Bin Blender:</b>				
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) ±10%		





**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
		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		
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		
<b>IPC Bin:</b>				
1.	Capacity	Volumetric: 260 L		
2.	Dimension	Diameter: 720 mm		



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
		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		
<b>Square Bin:</b>				
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		



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

**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		

**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.		



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
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.		

**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		
		<b>Working Capacity:</b> 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		



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
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		

**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		



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

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)	<b>IPC Bin and Square Bin:</b> Smooth and Mirror polished inside surface with no welding burrs and crevices. Corners shall be rounded		
2.	Outer Surface finish	<b>Pillar:</b> Dull polished & column inside portion is painted with epoxy paint.		

**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		



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

S.No.	Parameter	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
		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. "*****").		



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**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:

<b>S.No.</b>	<b>Document details</b>	<b>Required (✓ / ✗)</b>
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"/>





PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

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.



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**14.0 Abbreviations:** Full forms of all abbreviations are listed here.

<b>Abbreviation</b>	<b>Full form</b>
cGMP	: Current Good Manufacturing Practice
GEP	: Good electrical practices
AISI	: American Iron & steel institute
ISO	: International Standard Organization
L	: Litre
MOC	: Material of Construction
FLP	: Flame proof
L x B x H	: Length x Breadth x Height
Sr. No.	: Serial Number
SS	: Stainless Steel
URS	: User Requirement Specification
dia.	: Diameter
FAT	: Factory acceptance test
IPC	: In- Process Container
K.W.	: Kilo Watt
DQ	: Design Qualification
HP	: Horse Power





**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**16.0 Deviations/ Changes (if any):**

**17.0 Recommendations/ Conclusion :**



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
BIN BLENDER (PILLAR TYPE)**

**PROTOCOL No.:**

**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).

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