



PHARMA DEVILS

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

PROTOCOL No.:

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
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Document Reference: URS 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 prepare the detailed specification (Design data) for all major components of the equipment / system to ensure that the user requirement specification and Functional requirement specification or data sheet are achieved.

To design the equipment/ system in conjunction with the design data in order to provide basis for the vendor, manufacturer the design engineer for designing the system when the project begins.

3.0 SCOPE: The scope of this Design Qualification is that “**BIN BLENDER (PILLAR TYPE), Capacity: 600 Litres**” is designed and manufactured according to specified/ required standards and regulation.

4.0 Reason for DQ: To procure Bin Blender (Pillar type) with 600 litres capacity to be installed in Block-1 for homogeneous mixing/ blending of powders or granules.

The reason for preparing this document is:

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

- | | |
|---|-------------------------------------|
| Refurbished premises/equipment | <input type="checkbox"/> |
| Purchase of Utility Systems | <input type="checkbox"/> |
| Purchase of Process Equipment | <input checked="" type="checkbox"/> |
| Purchase of Laboratory Equipment | <input type="checkbox"/> |
| Bespoke or user configured computer systems | <input type="checkbox"/> |
| In-Use Systems that don't have a URS | <input type="checkbox"/> |
| Others (Specify) | <input type="checkbox"/> |

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

Refer attached DQ No.: _____.



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6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare, evaluate the design parameters with respect to User Requirement Specification (URS), Functional design specification, cGMP requirement and record the information
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

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



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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 Information of Input Material: The input material will be dried granules and lubricant.

9.0 Information of Output Material: The output material will be Blended material or lubricated granules.

10.0 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, etc.

S.No.	Parameter	Acceptance criteria (based on FDS / technical discussion)	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		



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S.No.	Parameter	Acceptance criteria (based on FDS / technical discussion)	Observation	Remark
		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		
3.	Weight (approx.)	4000 Kg Maximum		

11.0 Equipment Design and Principle of Working: NA

12.0 Process Description: For storage of material in the Square/IPC bin, tightly close the butterfly valve at bottom of the bin with clamp and open the upper lid of IPC Bin, then fill the Bin with material and close the lid with clamp. Attach the Bin to blender arm. Lift up to the blending height. Set the blending time. Start the blender. After blending time is over machine stops automatically in vertical position. That is outlet at bottom. After blending is over, take bin up to charging height. To take the discharge, keep the drum below it. Take down the empty bin and unlock.



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13.0 Functional Requirements of Equipment:

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

S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	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		
		Inside the drive frame to reduce the speed		
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	3 HP		
		Non Flame proof		
		On blending motor for stopping of motor		
7.	Hydraulic Power pack unit	Single station		
		Pump: 12 LPM		
		Pressure: 70 bar		
		Inside the control panel for		



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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
		operating hydraulic cylinder		
8.	Hydraulic Power pack motor	3 HP		
		RPM: 1440 (NOM) \pm 10%		
		Non Flame proof		
		Flange mounted		
		3 Phase		
		415 volt		
		50 Hz		
		On hydraulic power pack unit for supply of power to power pack		
9.	Hydraulic Cylinder	Flange mounted		
		Telescopic cylinder		
		Size: 150 & 95 mm dia bore, and 120 & 70 mm piston		
		990 mm Stroke		
		Inside the drive frame for upward and downward movement of arm		
10.	Hose pipe	Size: 3/8" BSP		
		3/8" Both side swivel nut, 3/8" BSP (F), SAE 100R2		
		MOC: Rubber		
		Quantity: 2 Nos.		
		Between cylinder to power pack for supply of oil from power pack to cylinder		
11.	A.C. Drive	3 HP		
		Inside the control panel for varying speed of blending motor		
12.	MMI	Model: Panel view -700		
		On the operating panel for operating the machine		



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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
13.	PLC	Model: Micrologix-1400		
		Inside the control panel for operating machine		
IPC Bin:				
1.	Capacity	Volumetric: 260 L		
2.	Dimension	Diameter: 720 mm		
		Height: 1298 mm		
3.	Trolley	Loose trolley for bin movement		
4.	Angle of cone	Shall be 60°		
5.	Outlet	150 dia. Butterfly Valve		
		On outlet bin		
6.	Cover	Shall be provided on bin		
7.	Transfer pot	Shall be provided at outlet of bin for transferring bin material into vibratory sifter		
8.	Castor wheel	100 dia x 32 W		
		Plate type, swivel- 2 Nos.		
		Plate type, swivel with brake- 2 Nos		
		On trolley for bin movement		
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.	Angle of cone	Shall be 60°		
5.	Valve	200 mm dia., butterfly valve		
		On outlet of bin		



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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
6.	Hand hole	350 dia. With cover		
7.	Vent	50 mm dia. TC with blank		
8.	Castor wheel	150 dia x 50 W		
		Plate type, swivel		
		On trolley for bin movement		

13.2 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 FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Pressure gauge for power pack	Shall be provided		

13.3 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 is also mentioned, if applicable e.g. temperature, RPM, pressure, etc.

S. No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Time	In Minutes/seconds.		
2.	RPM	In Numbers		



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13.4 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 FDS/ Technical specification/ Discussion)	Observation	Remark
1.	Data security facility	Access should be controlled through password protection.		

13.5 Performance Features: Mention in brief the performance requirements; the parameters that are planned to be evaluated during performance qualification and process validation activities are mentioned.

S. No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	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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13.6 Capacity / Speed: The desired capacity/speed with the UOM is specified in this section.

S. No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	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		

13.7 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 FDS/ Technical specification/ Discussion)	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	Shall be rounded		



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S.No.	Parameter	Acceptance Criteria (Based on FDS/ Technical specification/ Discussion)	Observation	Remark
	Bin			

13.8 System Boundaries: Nil.

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

S.No.	Parameter	Specifications/Dimension	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		
3.	Square Bin	Shell: SS 316		
		Cone: SS 316		
		Cover: SS 316		



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S.No.	Parameter	Specifications/Dimension	Observation	Remark
		Butterfly valve flap: SS 316		
4.	Gasket	Silicon/ Neoprene, Non – toxic, food grade.		

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

S.No.	Parameter	Specifications/Dimension	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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13.11 Electrical and Control Equipment Philosophy: A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

S.No.	Parameter	Specifications/Dimension	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.		

13.12 cGxP Considerations: The requirements for electronic compliance of the equipment.

S.No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Security Levels	Three Level Security should be provided (Operator, Officer and Admin)		
		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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14.0 Expected Documents and Drawings: Requirement of documents to be delivered by the suppliers 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"/>

✓ : Applicable & required ✗ : Not applicable

15.0 Available Utilities:

S. No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Electricity	Electrical supply three Phase		
		Frequency: 50 Hz		
		Voltage: 415 volts		
		Total consumption (approx): 6 HP		
		Neutral and earthing shall be provided.		
2.	Illumination of area	Not be less than 250 lux within the vicinity of the Rapid Mixer Granulator.		



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

S. No.	Parameter	Specifications/Dimension	Observation	Remark
1.	Maintenance	Easy accessibility for maintenance		
2.	Spare parts	List of spare parts and spare parts should be provided		

17.0 Delivery, Installation and Commissioning Requirements:

17.1 Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/supplier service engineer.

17.2 Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

17.3 FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

17.4 The manufacturer should install, qualify and commission the equipment at the user site and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of equipment.

18.0 Other Specific Requirements: To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

19.0 Reference Documents: Nil.

20.0 Abbreviations: Full forms of all abbreviations are listed here.

Abbreviation	Full form
--------------	-----------

cGMP : Current Good Manufacturing Practice

GEP : Good electrical practices

AISI : American Iron & steel institute



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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

21.0 Attachments: This section contains a list of all attachments referenced in the protocol.

S.No.	Attachment Details	Attachment No.

22.0 Recommendations/ Conclusion :



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23.0 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				