USER REQUIREMENT SPECIFICATION	
NAME OF ITEM: Bin Blender	**PROTOCOL No.....**
FUNCTIONAL AREA: Production	**Page No.:** 1 of 1

USER REQUIREMENT SPECIFICATIONS

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1.0 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**
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				

2.0 OBJECTIVE: The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the subject equipment and performance requirements for procurement of equipment including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP and cGEP.

This URS is an integral part of the procurement agreement with the supplier. The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

3.0 Scope: This user requirement specification (URS) is applicable for the procurement of Bin Blender (Pillar type).

4.0 Reason for URS: To procure Bin Blender (Pillar type) for installation 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	☐		
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 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To provide the User Requirement Specification (URS)
Engineering		To provide requirements with respect to utilities, components, based on the location of use and desired equipment parameters
Health Safety and Environment		To provide the safety requirements of equipment and facility
Quality Assurance		To be a part of qualification team
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

6.0 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 cladded 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.

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

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

9.0 **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	Specifications/Dimension
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.)	➢ NMT 3285 mm Length (Column to Bin) ➢ NMT 2035 mm Arm Width

		➢ NMT 2998 mm Height

10.0 Equipment Design and Principle of Working: NA

11.0 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.

12.0 Functional Requirements of Equipment:

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

S.No.	Parameter	Specifications
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	➢ Shall be provided
5.	Blending motor	➢ Shall be provided
6.	Brake for blending motor	➢ Shall be provided on blending motor
7.	Hydraulic Power pack unit	➢ Shall be provided for operating hydraulic cylinder
8.	Hydraulic Power pack motor	➢ Shall be provided
9.	Hydraulic Cylinder	➢ Shall be provided
10.	Hose pipe	➢ MOC: Rubber ➢ Quantity: 2 Nos. ➢ Between cylinder to power pack for supply of oil from

S.No.	Parameter	Specifications
		power pack to cylinder
11.	A.C. Drive	➢ Shall be provided
12.	MMI	➢ Shall be provided
13.	PLC	➢ Shall be provided
IPC Bin:		
1.	Capacity	Volumetric: 260 L
2.	Trolley	➢ Loose trolley for bin movement
3.	Outlet	➢ Shall be provided
4.	Cover	➢ Shall be provided on bin
5.	Transfer pot	➢ Shall be provided at outlet of bin for transferring bin material into vibratory sifter
6.	Castor wheel	➢ 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.	Working capacity	➢ Maximum: 420 Liters (250 kg @ 0.6 BD) ➢ Minimum: 210 Liters (125 kg @ 0.6 BD)
3.	Valve	➢ Shall be provided
4.	Hand hole	➢ Shall be provided
5.	Vent	➢ Shall be provided
6.	Castor wheel	➢ Plate type, swivel shall be provided on trolley for bin movement

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

S.No.	Parameter	Specifications
1.	Pressure gauge for power pack	Shall be provided

12.3 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 mentioned, if applicable e.g. RPM, Time duration.

S.No.	Parameter	Specifications
1.	Time	In Minutes/seconds.
2.	RPM	In Numbers

12.4 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	Specifications
1.	Data security facility	Access should be controlled through password protection.

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

S.No.	Parameter	Specifications
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.

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

S.No.	Parameter	Specifications
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 ± 2 RPM ➢ Variable from 2 to 10 RPM

15.0 Automation and Safety Features: Adequate safety feature for men and material shall be provided along with the equipment. 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/ Blending activities, etc.

S.No.	Parameter	Specifications
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

16.0 System Boundaries : NA

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

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

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

S.No.	Parameter	Specifications
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.

19.0 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. The electrical system of the equipment shall be housed as per the cGMP and cGEP.

S.No.	Parameter	Specifications
1.	PLC System	➢ 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.

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

S.No.	Parameter	Specifications
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. "**********").

21.0 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	☑
2.	Functional Specifications	☒
3.	PLC Alarm/Interlock/Safety/ communication/power failure test procedures	☑
4.	Piping and Instrumentation Diagram (P&ID)	☒
5.	Instrument Listing	☑

S.No.	Document details	Required (✓ / ×)
6.	Control Schematics	☒
7.	Control Panel Assembly Drawings	☒
8.	Machine Assembly Drawings	☒
9.	Bill of Materials	☒
10.	Operator, Maintenance and Service Manuals	☑
11.	Spare Parts List	☑
12.	MOC certificates	☑
13.	Calibration certificates of instruments	☑
14.	Test certificates of components/test devices	☒
15.	Weld certificates (if any)	☒
16.	'As-built' P&ID	☒
17.	GA drawing	☑
18.	Isometric drawing (if any)	☒
19.	Electrical drawings	☑
20.	Component Cut Sheets (optional)	☒
21.	PLC Program Printouts and Disk File (optional)	☒
22.	HMI Configuration Printout and Disk File (optional)	☒
23.	Other (Specify)	☒

✓: Applicable & required × : Not applicable

22.0 Available Utilities:

S.No.	Parameter	Specifications/Dimension

S.No.	Parameter	Specifications/Dimension
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.

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

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

24.0 Delivery, Installation and Commissioning Requirements:

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

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

24.3 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.

24.4 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.

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

26.0 Reference Documents: Nil.

27.0 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
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

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

S. No.	Attachment Details	Attachment No.

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Bin Blender	**PROTOCOL No.....**
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S. No.	Attachment Details	Attachment No.