DESIGN QUALIFICATION (DQ)

TABLE OF CONTENT

1.0 OBJECTIVE:

To design, engineer, and supply the High Shear Mixer Granulator as per cGMP and cGEP guidelines and to provide assurance that the machine is manufactured as per the URS and it complies with the Scope of Supply.

To prove that each operation proceeds as per the design specification and the tolerances prescribed there in the document, are the same at utmost transparency. Validation procedure is set for complete satisfaction of the customer & building confidence of the user about the machine.

2.0 SCOPE:

The scope of this qualification document is limited to the Design Qualification of High Shear Mixer Granulator. This qualification document is part of a validation activity for the High Shear Mixer Granulator.
Qualification of support utilities is not within the scope of this qualification document.

The equipment shall be used for granulation of different powders to be used in the formulation. The equipment shall operate under dust free environment and conditions as per the GMP requirements.

3.0 RESPONSIBILITIES:

CLIENT:

1. To provide the URS for the equipment.

2. To perform the Factory Acceptance Test (FAT).

MANUFACTURER:

1. To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification viz.

(i) Machine overview,
(ii) P&ID drawing,

(iii) Equipment orientation with layout,
(iv) Specifications of the sub-components/ bought out items, and their make, model & quantity, and backup records/ brochures,
(v) Details of Utilities,
(vi) Identification of components for calibration
(vii) Material of construction of all components
(viii) Brief process description
(ix) Safety features and alarms
(x) Pre-installation requirements

2. To facilitate the client for the Factory acceptance test of the machine at their works/ site.

3. To confirm the safe delivery of the equipment to the user site.

4. To ensure that no un-authorized and / or unrecorded design modifications shall take place. If at any point in time, any change is desired in the mutually agreed design, Change control procedure shall be followed and documented.

5. To ensure the proper installation and commissioning of the equipment.

4.0 USER REQUIREMENTS SPECIFICATION (URS):

DESCRIPTION	SPECIFICATIONS
Equipment	High Shear Mixer Granulator
Specification	Flame proof construction as per Annexure – II & Annexure – III to Purchase Order.
Capacity	600 Litters
Model	• The equipment should be a cGMP model, single piece construction without flange joint, compliant with contact-specific SS316L parts. • Separation of service parts (e.g. drives) from processing zone, to enhance the cGMP. • Ease of cleanability.
Process	Equipment should be able to perform granulation.
Material of construction	• All contact parts, lid, shell, cone, base plate, impeller, chopper should be made up of SS 316L & all other non-contact components are of SS 304. • Main frame M.S. with SS304 guards. • Material test certificates to be provided.

DESCRIPTION	SPECIFICATIONS
Calibration	• All components that require calibration shall be identified and calibrated. • Calibration certificates to be provided at the time of Installation qualification. • Test certificates / calibration charts of sensors & control instruments to be provided.
Qualifications/ Documentation	• The manufacturer shall complete and provide the documents pertaining to Design, Installation & Operation Qualification and detail functional specifications including control system with screen design of operating terminal. • Alarms & Interlocks. • Information on purchased/bought-out parts. • Circuits & interlocks details.
Safety features	• Adequate safety features for men and material shall be provided along with the equipment. Flameproof motors and controls.
Control system	The equipment shall be controlled through PLC based system.
Electrical system	• The electrical system of the equipment shall be housed as per the cGMP and cGEP standard, with adequate safety • Electrical panel is to be installed in service area.

5.0 MACHINE DESCRIPTION:

5.1 Process Equipment Description

The High Speed Mixer Granulator (HSMG) is basically designed by the manufacturer for batch processing to produce granules from pharmaceutical bulk powders. The capacity as designed can hold a maximum of 600 litters as its bowl volume. The working volume however will be 500 litters.

All the contact parts will be made out of SS 316L. Effective sealing arrangements at the impeller and chopper shafts further support this.

Electronic safety switches are provided for the interlocking system for Motor and guards.

The entire operation is operated and controlled through a Programmable Logic Control.

A programmable logic controller (PLC) will execute the direction of the sequence of operation. The PLC is of Mitsubishi making model Fx2N series. The complete set of control system includes field sensors, PLC system, printer interface (optional) and command panel. Main control system having features like detailed alarm messages, integrated operator guide, small command panels, small command panels etc.

5.2 PLC Description

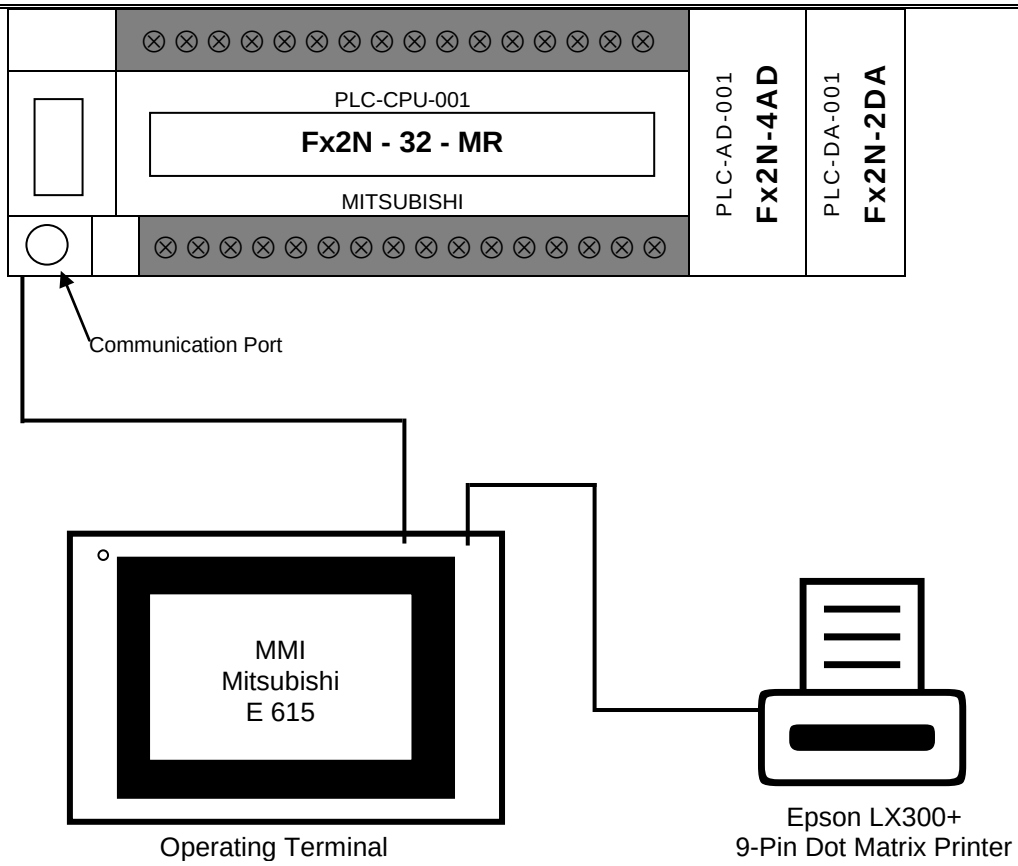
The main function of a PLC is to translate the instructions into the digital or analog codes needed to operate the device or machine.

The main function of this PLC system is to collect data from field instrumentation & display the information on the operator station. The instruments are connected to the system equipment and piping. The collected data will be utilised by the PLC for process control.

The user interface, based in an industrial type MMI, will assist the operator to supervise and control the process. Based on the displayed information the operator, by means of the user interface, can provide commands to the PLC.

The PLC then executes the operator instructions. A Mitsubishi Family Fx2N PLC has been chosen as the Central Processing Unit (CPU).

The PLC system layout for the HSMG machine automation is as shown below:



The controller software generated, for the HSMG600 machine automation has been developed in ladder logic language using MEDOC 2.30 English.

6.0 TECHNICAL SPECIFICATIONS:

Bowl	• 600-Liter Gross Volume. • Manufactured from Stainless Steel 316L. • Cylindrical-Conical Shape. • With Discharge port.

DESIGN QUALIFICATION (DQ)

Bowl Lid	• Pneumatic Cylinder assisted lid. • 4 Nos manual quick acting locks. • Vent Filter is provided. • Glass Inspection window. • Port for Liquid/ Binder charging. • Flameproof, Illumination Light.
Impeller	• 3 – Blade Impeller. • Stainless Steel 316L. • Mounted on a double ball bearing assembly. • Shaft sealed via air-purged seals.
Impeller Drive	• Flameproof Motor, 50 HP, 1440 RPM with variable frequency drive. • Drive transferred via a "V" Belt to the Gearbox.
Chopper	• 4 Blade Chopper. • Stainless Steel 316L. • Laterally mounted on the bowl. • Shaft sealed via air-purged seals.
Chopper Drive	• Flameproof Motor, 5/7.5 HP, 1440/2880 RPM. • The motor is a dual speed motor. • Directly coupled drive.
Power Panel for PLC and Power Components	• One power panel powder coated, 16SWGthick mild steel, foot mounted, self-supporting type, for installation in the service area. The same will consisting of: • Mitsubishi PLC & low voltage components. • Motor Contactors. • Ammeter. • Indication lamps. • Cooling Fan & Filters. • MCBs. • Voltmeter • Emergency Push Button..

DESIGN QUALIFICATION (DQ)

PLC Controls	• 3 Levels of password for Manager, Supervisor & Operator with access control. • Failure Diagnostics/interlocks menu for individual device to be provided in the Operator Interface. • Discharge Gate Controls. • Control for purging air for Impeller/ Chopper. • Alarm Display for Machine Stoppage Reason. • Low Compressed Air. • Lid/ Guards Open. • Main Motor Overload. • Consecutive errors. • Machine set parameters/ function switches on the screen. • Remedy for alarm on the screen. • Recipes for different products.
Control Panel	• Separate Panel made of Stainless Steel 304. • "E615" Human Machine Interface with complete Mimic Graphics & programming to allow process management & diagnostics will be supplied. • No cables or pneumatic piping is supplied along with standard supply.
Pneumatic Panel	• One machine mounted pneumatic assembly, containing the following; • Pressure Gauge for monitoring the pneumatic pressure for machine operation. • Solenoid Valves & Solenoid Coils
Structure	• Structure manufactured from MS. • Guards, Stainless Steel 304, are interlocked. • Stainless Steel 304 chequered sheet on platform. • Mounted on anti vibration mounts.

7.0 TECHNICAL SPECIFICATIONS OF COMPONENTS & SUB - COMPONENTS USED / BOUGHT OUTS

Sr.No.	DESCRIPTION	SPECIFICATIONS
1. Equipment Description		
	Name	High Shear Mixer Granulator
	Specification	Flame proof construction
	Capacity	600 Litters
	Model	HSMG600, GMP model.
	Overall dimensions	2675 L x 2480 W x 3450 H [mm]
	Weight	Machine : 2500 Kg, Approx
2. Support Structure		
	Manufacturer	Manufacturer Name
	Material	Mild Steel
	Guards	SS304, 16 SWG
	Surface Finish	Matt Finish 0.85 Ra
3. Lid		
	Manufacturer	Manufacturer Name
	Material	Stainless Steel 316L
	Thickness	6 mm
	Rim	20 mm
	Surface Finish Inside	0.35 Ra
	Surface Finish Outside	0.85 Ra
	Material – Sealing	Silicon Gasket
	Port for liquid addition	Yes
	Port for material charging	Yes
	View window	Yes with scrapper
Sr.No.	**DESCRIPTION**	**SPECIFICATIONS**
4. Shell		
	Manufacturer	Manufacturer Name
	Material	Stainless Steel 316L
	Thickness	6 mm

	Surface Finish Inside	0.35 Ra
	Surface Finish Outside	0.85 Ra
5. Cone		
	Manufacturer	Manufacturer Name
	Material	Stainless Steel 316L
	Thickness	8 mm
	Surface Finish Inside	0.35 Ra
	Surface Finish Outside	0.85 Ra
	Welds Inside Polished	Yes
6. Impeller		
	Manufacturer	Manufacture Name
	Material	Stainless Steel 316L
	Blades	Three
	Surface Finish	0.35 Ra
7. Chopper		
	Manufacturer	Manufacture Name
	Material	Stainless Steel 316L
	Blades	Four
	Surface Finish	0.35 Ra
8. Bottom		
	Manufacturer	Manufacture Name
	Material	Stainless Steel 316L
	Thickness	8 mm
	Surface Finish Inside	0.35 Ra

Sr.No.	**DESCRIPTION**	**SPECIFICATIONS**
9. Chequered Plate		
	Position	On Machine Platform
	Manufacturer	Manufacture Name
	Material	Stainless Steel 316L
	Thickness	2mm
10. Impeller Motor		
	Make	Crompton
	Class	I, High Efficiency
	Insulation	Class 'F'
	Type	Flameproof

	Motor KW/HP	50 HP
	Motor RPM	1440
	Phase	3 Phase
	Voltage	3 x 440V
	Frequency	50 Hz
11. Chopper Motor		
	Make	Crompton
	Class	I, High Efficiency
	Insulation	Class 'F'
	Type	Flameproof
	Speed	Dual
	Motor KW/HP	5.0/7.5 HP
	Motor RPM	1440/2880
	Phase	3 Phase
	Voltage	3 x 440V
	Frequency	50 Hz

12. Pressure Gauge		
	Quantity	2 Nos.
	Specification	for purging air, & with FRL unit
	Position	One Guard, one with FRL unit.
	Manufacturer	FESTO
	Specification	0 - 10 bar
	Model No.	FMA - 50 - 1/4 – 16
	Input Range	0 – 10 bar
	Accuracy	± 0.5 bar
13. Ammeter		
	Position	On Control Panel
	Manufacturer	Enrecon
	Type	Digital with inbuilt selector switch
14. Voltmeter		
	Position	On Control Panel
	Manufacturer	Enrecon
	Type	Digital with inbuilt selector switch
15. PLC		
	CPU Make	Mitsubishi
	Model	Fx2N-32-MR
	PLC Input / Output	16 Input / 16 Output
16. Analog Input Card		
	Quantity	1 No.
	Make	Mitsubishi
	Model	Fx2N-4AD
	Channels	4 Channel
	Specification	Analog to Digital
Sr.No.	**DESCRIPTION**	**SPECIFICATIONS**
17. Analog Output Card		
	Quantity	1 No.
	Make	Mitsubishi
	Model	Fx2n-2DA

	Channels	2 Channel
	Specification	Digital to Analog
18. MMI		
	Make	E terminal E615
	Manufacturer	Beijer Electronics AB
	Front panel, WxHxD	200 x 150 x 5.0 [mm]
	Front panel seal	IP 65, NEMA 4, NEMA 4X
	Rear panel seal	IP20
	Keyboard material	Membrane keyboard with polyester snap discs
	Reverse side material	Yellow-chromated steel plate
	Weight	1.5 kg
	Serial port RS-422	25-pin D-sub contact, female
	Serial port RS-485	4-pin jack connection block, male
	Serial port RS-232	9-pin D-sub contact, male
	Flash memory	400 kb
	Real time clock	Yes
	Display	LCD display, 320 x 240 pixel, 256 colours graphic and text.
	Contrast setting	Programmable
	Supply Voltage	+24 VDC, 3-pin jack connection block.
19. Printer		
	Make	Epson
	Model	LX-300+
	Specification	9-Pin Dot Matrix Printer
Sr.No.	**DESCRIPTION**	**SPECIFICATIONS**
20. Variable Frequency Drive for Impeller		
	Manufacturer	Mitsubishi
	Capacity	50 HP
21. Control Panel		
	Manufacturer	Manufacture Name
	Material	Stainless Steel 304
	Finish	0.85 Ra (Matt)
	Air Purged	Yes
	Cover	Polycarbonate

	Location	Equipment Mounted
22. Electrical Panel		
	Manufacturer	Manufacturer name
	Material	MS, Powder Coated RAL 7032
	Thickness	16 SWG
	Door	Single
	Location	Service area

8.0 DETAILS OF UTILITIES

DESCRIPTION	SPECIFICATIONS
1 Electrical	
Phase	3 Phase
Voltage	440V
Frequency	50 Hz
2 Compressed Air	
Flow pressure	6 bar (Kg)
Quality	oil, water & dust free
Residual moisture content	< 5.5 g/m^3
Particle size	0.1 um
Residual Oil	< 1 ppm

Max. Consumption	210 m^3/Hr

9.0 IDENTIFICATION OF COMPONENT FOR CALIBRATION

In the High Shear Mixer Granulator, following are the components, which needs calibration. They shall be calibrated during/ before installation of the equipment at the site:

Following are the components:

1. Pressure Measurement (Purging Air)

10.0 MATERIAL OF CONSTRUCTION

S.NO	COMPONENT DESCRIPTION	MOC
1.	Structure	MS
2.	Guards(Side Covers)	SS 304
3.	Lid	SS 316L
4.	Cone	SS 316L
5.	Bottom	SS 316L
6.	Clamping Assembly	SS 304
7.	Ladder	SS 304
8.	Railings	SS 304
9.	Bolts & Nuts (Dome Type)	SS 304
10.	Gasket (Food Grade)	Silicon
11.	Control Panel	SS 304

12.	Electric Panel	MS, Powder Coated RAL 7032
13.	Transparent Covers	Polycarbonate

11. P&ID DIAGRAM FOR REFERENCE & APPROVAL

Attached as annexure-…….

Approval status: APPROVED/ NOT APPROVED

Any change in the approved diagram: Yes/ No.
If yes, the reason for change
……
……
……
……

12. EQUIPMENT ORIENTATION WITH ROOM LAY OUT:

Attached as annexure-…….

Approval status: APPROVED/ NOT APPROVED

Any change in the approved orientation layout: Yes/ No.
If yes, the reason for change
……
……
……
……

13.0 BRIEF PROCESS DESCRIPTION

13.1 Purpose of High Shear Mixer Granulator

The purpose of a High Shear Mixer Granulator is to produce granules from pharmaceutical bulk powders.

This is attained by efficient mixing of the powders with liquid binder by the bottom impeller & a chopping effect is given to the material by the tangentially attached chopper for achieving the level of agglomeration.

14.0 SAFETY FEATURES AND ALARMS:

14.1. Sealing System

The sealing system of this machine consists of the following:
- Gasket on Lid
- Magnetic Switches on the bowl & Lid

14.2. Burn Hazard

A surface temperature of > 80° C but < 100° C (depends of the pre-selected inlet air temperature) can be expected at the inlet air ducts and other components located behind the heater. Accordingly, appropriate insulation of these parts is recommended to prevent injury and to avoid heat losses.

14.3. Alarm / Fault Administration

Following are the list of alarms that are incorporated for the safety of the equipment and the operators:

If any of the following error through alarm occurs that alarm indication LED on MMI blinks along with an audio sound of the buzzer. Also on the display screen the word "Alarm" will flash. The process will be switched OFF automatically and the LED corresponding to the process will turn "RED". The operator that has to press the key "List and display will switchover to the alarm monitoring screen that will guide operator about the error(s) occurred.

The operator then has to attend to the specific problem. After taking the appropriate action, the "Alarm / Ack" button has to be pressed that will make the sign of "Alarm" from the screen disappear with the flashing Red LED will turn GREEN. The process will not start until the operator presses the "Process ON" button. At the time of shutdown, the process time counters stops and is restarted only when the operator presses the "Process ON" button. This ensures that the actual time taken by the process is recorded and the shutdown time is ignored. The facility of alarm printing is also provided to have a record of details of the alarm occurred (description, date & time) and a reprint of the date and time when the acknowledgment button has been pressed.

LIST OF ALARMS:

Sr. No.	Alarm Message	Description
1.	Purging Air Pressure Low	If the air pressure drops below the minimum set level, then this alarm will trip the machine.
2.	Guards Open	If the Guards are open the machine will not start If closed system is open then this alarm will generate and trip the process.
3.	Discharge Gate Open	If the discharge gate is open the machine will not start. (Separate window provided for discharge mode to enable chopper & Impeller run at time of discharge)
4.	Machine Stoppage	If emergency stop is operated the alarm will generate.
5.	Main Motor Overload	If the Impeller motor is overload the alarm will generate and trip the process.
6.	Main Motor Overload	If the Chopper motor is overload the alarm will generate and trip the process.
7.	Batch Completion	When the batch is completed the alarm will generate and trip the process.

15.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of erection work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report
4. Pre-installation requirements
5. Final report

16.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined Change control procedure.

17.0 DESIGN QUALIFICATION REPORT APPROVAL

17.1 Summary:

17.2 Certification:

18.0 APPENDIX

18.1 LIST OF ABBREVIATIONS

cGMP	current Good Manufacturing Practices
GEP	Good Engineering practices
AISI	American Iron & Steel Institute
MS	Mild steel
FLP	Flame Proof
SS	Stainless Steel
CFM	Cubic Feet Per Minute
KW	Kilo Watt
DQ	Design Qualification
HMI/MMI	Human/Man Machine Interface
FAT	Factory acceptance test

DESIGN QUALIFICATION (DQ)

18.2 REFERENCE DOCUMENTS

1. Manufactures Brochure (s) / Manual (s). (Title and Location).

To be supplied with the Installation qualification documents

1. Instruction & Maintenance manual
2. Calibration certificates
3. Material of construction certificates
4. Instruction manual for PLC
5. Test certificates of all motors

2. Purchase Order Attached (Yes / No). If no, state Location.

Yes – Attached with DQ Document

Remarks (if any) :

18.3 ANNEXURE LIST

S.NO.	DESCRIPTION	ANNEXURE NO.
1.	FAT Report	
2.	Equipment Brochure	
3.	Purchase Order (Including Annexure to Purchase Order – I, II & III)	
4.	Scope of Supply	
5.	Approved Equipment Room Lay out	
6.	P& I diagram of FBE 500	
7.	Circuit Diagram – control panel	