DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

RAPID MIXER GRANULATOR

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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PROTOCOL CONTENTS

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1.0 PROTOCOL PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Rapid Mixer Granulator with cGMP Model procured from **Elicon Pharma** for ……..
- Equipment Transfer from Plant.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification Protocol cum Report. • Assist in the Preparation of Design Qualification Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/ bought out items, their Make, Model, ➢ Details of Utilities. ➢ Material of construction of all components. ➢ System Description. ➢ Safety Features and Alarms. • Review of Design Qualification Protocol cum report after Execution.

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5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no Un-authorized or unrecorded design modification 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.

6.0 BRIEF EQUIPMENT DESCRIPTION:

RMG or high sear machine is a very precision machine, performing dry mixing and wet granulation in the same bowl in only 6 to 20 min. the entire operation is fully dust free and automatic including discharge. All parts coming in contact with mix area of stainless AISI 316 L quality and are highly polished.

Basic machine consist of base frame made from MS angle and channels. Top of the frame is covered by one big MS plate. Complete base frame is Cladded by SS sheet. Top plate is Cladded by 1.5 mm thick SS embossed sheet for anti- slip property and easy cleaning. Mixing bowl is fixed on top of this plate. There are two impellers inside the bowl. Main impeller run in horizontal plane and chopper granulation impeller run in vertical plane. Top lid is operated pneumatic Festo cylinder. Main impeller is support on main shaft, which has its special Z type housing. Z type housing totally eliminates any chance of cross contamination of product mix with bearing lubricants. Z type housing cap contains PTFE and Labyrinth seal along with air purging facility totally eliminates cross contamination. Chopper blades are directly mounted on chopper shaft. Chopper housing is entirely made of AISI 316 L having air purging and special seals. Main impeller is having unique design and blade angle, thus pushing the material radial direction. Machine has a discharge outlet with pneumatic cylinder. Discharge piston has profile exactly matching with the vessel interior, giving a perfect sealing arrangement.

CHARGING AND DRY MIXING

Pre- weighed raw material is charged through the charging port located on the top lid of the RMG bowl. Once charged the dust proof charging interface is manually disengaged and the charging hole is sealed shut. All machine safety control is activated.

Main impeller and chopper are operated in slow speeds through PLC and hen in fast speed as per process requirement. Duration of total process time is timer controlled.

WET MIXING/ GRANULATION

Binder thus added into the mass by slow/fast operation of the main impeller with concurrent operation of the chopper results in dough formation. This operation is on a timed cycle basis and is continuously monitored by the operator through the ampere meter reading which is displayed on the operating panel of the RMG.

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7.0 EQUIPMENT SPECIFICATION:

Equipment Specification is based on User Requirement Specification document is prepared by …….

The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 EQUIPMENT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Rapid mixer granulator should be able to mix dry powders or blends and granulating the materials.	Rapid mixer granulator should meet the requirement for mixing of dry powders or blends and granulating the material in formulation plant.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	3 Phase Voltage-415 V Frequency-50Hz±5%	cGMP Requirement
Compress Air Supply		
Consumption	20 meter Cube per hour	cGMP Requirement
Flow Pressure	6 Kg/cm^2	cGMP Requirement
Quality	Oil, Water & Dust Free	cGMP Requirement

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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

COMPONENTS/PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
Equipment Description	Name : Rapid mixer granulator Model : cGMP 600 L	Design Requirement
Gross Capacity	600 L	Design Requirement
Working Capacity	480 L	Design Requirement
Net Weight	3500 Kgs	
Overall Dimension	Length : 3000 mm Width : 2850 mm Height : 3600 mm	Design Requirement
Dimension for RMG Bowl	Height : 725 mm (from outside) Inner Dia : 920 mm (At Top) Inner Dia : 1200 mm (At Bottom)	Design Requirement
Other dimensions as per Drawing	Should be as per the specification mentioned in drawing	Design Requirement
Working Capacity	240 Kg (including binder. Total wet mass)	Design Requirement
Main Motor	Make : Hindustan HP : 40/50 HP RPM : 730/1470 Volt : 415±10% Hz : 50±5% Phase : 3 Sr. No. : 63197	Design Requirement
Chopper Motor	Make : Hindustan HP : 5/7.5 Volt : 415 ± 10 % Hz : 50 ± 5% Phase : 3 RPM : 1430/2900 Sr. No : 407457	Design Requirement
Gear Box	Make : Elicon Size : 8''	Design Requirement

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COMPONENTS/PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
	Ratio : 10:1 S.No. : 453662	
Clearance of main impeller from bottom of bowl	1 to 2 mm	Design Requirement
Clearance of main impeller from side of bowl	5 to 7 mm	Design Requirement
Location of chopper	155 mm from bottom of bowl	
PLC	Make : Allen	Design Requirement
LID Lifting Cylinder	Make : Dancal India Stroke Length : 500 mm	Design Requirement
Discharge Piston Cylinder	Make : Dancal India Stroke Length : 300 mm	Design Requirement
V - Belt	B-139 (3Nos)	Design Requirement
Gasket	Make : SU.Icon	Design Requirement
Pulley for Motor	Make : 12”Dia 3 Step	Design Requirement
Relay Card	Make : Omron	Design Requirement
Main bowl	Bottom thickness : 6 mm Shell of the bowl : 5 mm Cone of the bowl : 5 mm Lid of the bowl : 5 mm Rim of the bowl : 20 mm	Design Requirement
Stand or Platform	From MS (angle and channel), Cladded suitably from outside by 16 swg, 1.5 mm thick, S.S. 304 sheets completely welded all around, flush type of SS 304 covers. Dimension of the platform are as per G.A. drawing top cladded sheet of the platform is dimpled SS 304 to have anti slip property.	Design Requirement
Staircase and Railing	**Staircase** Make: SS 304 **Railing** Make : SS pipe make:	Design Requirement

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COMPONENTS/PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
	Size: 38 mm diameter.	
Main Impeller	Blade: 3 Nos. MOC: AISI 316L	Design Requirement
Chopper Impeller	Blade: 2 Nos. MOC: AISI 316L	Design Requirement
Discharge Assembly	It is with pneumatic discharge piston which matched the interior vessel.	Design Requirement
Electric Panel and Control panel.	Complete operating panel of SS 304 in 16 gauge having display MMI E 1061. Both Auto & Manual mode to be provided for machine with PLC only. Complete flexibility will be provided for operator for his ease and convenience. Main service made up of mild steel, powder coated to be kept in service area.	Design Requirement
Mixing Tool Lift	Provided using manual power pack to avoid jerk during impeller lift.	Design Requirement

8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MOC
1.	Stand	AISI 304
2.	Main Bearing house	AISI 304
3.	Chopper Housing	AISI 316
4.	Staircase and Railing	SS 304
5.	'V' Belt	Rubber
6.	Bowl	AISI 316
7.	Top Lid	AISI 316
8.	Filter 5 Micron	AISI 316
9.	Chopper Blade	SS 316
10.	Discharge Piston	AISI 316
11.	Control Panel with PLC	AISI304
12.	Safety Rail	AISI304
13.	Motor	C.I.

8.5 SAFETY:

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
1.	Main Air Pressure low	Machine should not Start	Safety Requirement
2.	Top Lid is open.	Machine should not Start	Safety Requirement
3.	Discharge port is open	Machine should not Start	Safety Requirement
4.	Main impeller blade is lifted	Machine should not Start	Safety Requirement
5.	Discharge of Material will not occur if FBD trolley is not beneath discharge opening.	Machine should not Start	Safety Requirement
6.	Main motor tripped	Machine will not run	Safety Requirement
7.	Chopper motor tripped	Machine will not run	Safety Requirement
8.	Discharge open for cleaning	Machine will not Run	Safety Requirement
9.	Emergency push button pressed	Machine will not run.	Safety Requirement

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Rapid mixer granulator machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement.

(2) Operation and service manual for Rapid Mixer Granulator.

Verified By
(Quality Assurance)
Sign/Date: .....

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9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

C.I.	:	Cast Iron
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
db	:	Decibel
Dia	:	Diameter
DQ	:	Design Qualification
FBD	:	Fluid Bed Drier
GA	:	General Arrangement
GB	:	General Block
HP	:	Horse power
ID.	:	Identification
kg	:	Kilogram
KW	:	Kilo watt
L	:	Liters
MCB	:	Miniature Circuit Break
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
NLT	:	Not Less Than
P & ID	:	Piping and Instrumentation Diagram
PLC	:	Programmable Logical Control
PO	:	Purchase Order
PTS	:	Powder Transfer System
RH	:	Relative Humidity
RMG	:	Rapid Mixer Granulator
SS	:	Stainless Steel
URS	:	User requirement specification
V	:	Voltage

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			