



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
RAPID MIXER GRANULATOR**

<b>EQUIPMENT ID No.</b>	
<b>LOCATION</b>	
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**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)			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of Rapid Mixer Granulator to be used for mixing of powder or blends and granulating the materials in formulation Plant.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment Safely, Effectively and Consistently.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to qualification of **Rapid Mixer Granulator (Make- Elicon Pharma, Capacity- 600 liter)** to be installed in the .....
- Equipment Transfer from Plant.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post Approval of Installation Qualification Protocol cum report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Installation Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Installation Qualification Protocol cum report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Installation Qualification Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Installation Qualification Activity.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Installation Qualification Protocol cum report after Execution.</li></ul>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Rapid Mixer Granulator
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	Elicon Pharma
<b>Supplier's Name</b>	Elicon Pharma
<b>Location of Installation</b>	

**6.0 SYSTEM 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 are 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. This is achieved through IPC Bin/paste kettle using a material handling device.

Once charged the dust proof charging interface is manually disengaged and the charging hole is sealed shut. All machine safety control is activated.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

Main impeller and chopper are operated in slow speeds through PLC and then 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.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents :**

- Executed and approved design qualification document.
- Piping and Instrumentation Diagram (P& ID).
- Electrical Circuits Diagram.
- Technical Specification of Equipment.
- Certificate of Material of Construction of Components.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

- All the documents should be available, complete and approved by respective authorities.





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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks & Location:**

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be grouted and mounted properly.		
Leveling	Should be properly balanced and leveled.		
Edges of Parts	Metal edges should be properly Rounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	.....		
Illumination in area	NLT 300 Lux.		
Working space around the equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**Checked By (Production)**  
**Sign/Date:** .....

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

**Inference:**

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**Reviewed By (Manager QA)**  
**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.2 UTILITIES REQUIRED:**

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	3 Phase Voltage- 415 V $\pm$ 10 % Frequency- 50 Hz $\pm$ 5 %		
<b>Compressed Air</b>			
Flow Pressure	6 bar (kg/cm <sup>2</sup> )		
Quality	Oil, Water & Dust free		
General method of the electrical wiring	A. No loose hanging cables B. Well-insulated electrical wirings. C. Located in a safe place well protected from water leakage during machine cleaning and also safe for operator during Operation.		

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.3 MOC Verification List:**

S.No.	COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
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.		

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(Manager QA)**

**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.4 Drawing Verification:**

<b>REFERENCE ENGINEERING DRAWINGS</b>	<b>AVAILABLE (YES/NO)</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
General arrangement Diagram		
Power Circuit Diagram		
Pneumatic Diagram for Solenoid valve		
Panel Physical Layout		
Circuit Diagram for PLC Controls		

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**(Quality Assurance)**  
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**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.5 EQUIPMENT VERIFICATION:**

**8.5.1 Technical specifications:**

COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
<b>Equipment Description</b>	Name: Rapid mixer granulator Model: cGMP		
<b>Gross capacity</b>	600 L		
<b>Working Capacity</b>	480 L		
<b>Overall Dimension</b>	Length : 3000 mm Width : 2850 mm Height : 3600 mm		
<b>Platform</b>	Height : 1325 mm		
<b>Discharge port</b>	Inner Dia : 253 mm		
<b>Other dimensions as per Drawing</b>	Should be as per the specification mentioned in drawing		
<b>Main motor</b>	Make : Hindustan HP : 40/50 HP Volt : 415±10% Hz : 50±5% Sr.No : 63197		
<b>Chopper motor</b>	Make : Hindustan HP : 5/7.5 HP Volt : 415 ± 10 % Hz : 50 ± 5% Phase : 3 RPM : 1430/2900 Sr.No : 407457		
<b>Lid Lifting Cylinder</b>	Make : Dancal India StrokeRange: 500 mm		
<b>Gear Box</b>	Make : Elicon		



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COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size : 8" Ratio : 10:1 Sr.No : 453662		
<b>Clearance of main impeller from bottom of bowl</b>	1 to 2 mm		
<b>Clearance of main impeller from side of bowl</b>	5 to 7 mm		
<b>Location of chopper</b>	155 mm from bottom of bowl		
<b>PLC</b>	Make : Allen Size : 6"		
<b>Main bowl</b>	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		
<b>Stand or platform</b>	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.		
<b>Staircase and railing</b>	<b>Staircase</b> Make: SS 304 <b>Railing</b> Make : SS pipe make:		



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COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size : 38 mm diameter.		
<b>Main impeller</b>	Blade: 3 Nos. MOC: AISI 316L		
<b>Chopper impeller</b>	Blade: 2 Nos. MOC: AISI 316L		
<b>Discharge assembly</b>	It is with pneumatic discharge piston which matched the interior vessel.		
<b>Electric panel and Control panel.</b>	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.		

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**(Quality Assurance)**

**Sign/Date:** .....

**Reviewed By**

**(Manager QA)**

**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.6 INSTALLATION CHECKS:**

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Identification and verification of major and sub components of Rapid mixer granulator.		
2.	Verification of system utility requirements.		
3.	Check that all bolts are properly tightened.		
4.	Ensure all Electric connections done properly.		
5.	Ensure all mechanical adjustment.		
6.	Check that all Pneumatic connections are properly fitted.		

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**Sign/Date:** .....





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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**8.7 SAFETY:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Air Pressure low	Machine should not Start		
Top Lid is open.	Machine should not Start		
Discharge port is open.	Machine should not Start		
Main impeller blade is lifted.	Machine should not Start		
Discharge of Material will not occur if FBD trolley is not beneath discharge opening.	Machine should not Start		
Main motor tripped.	Machine will not run		
Chopper motor tripped.	Machine will not run		
Discharge open for cleaning.	Machine will not Run		
Emergency push button pressed.	Machine will not run.		

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**(Production)**  
**Sign/Date:** .....

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**(Quality Assurance)**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Validation Master Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection

**10.0 DOCUMENTS TO BE ATTACHED:**

- Certificate of MOC.
- Operation and Maintenance Manual.

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

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

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**16.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
GB	:	General Block
HP	:	Horse power
Hz	:	Hertz
Id	:	Inner diameter
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilogram
KW	:	Kilo watt
Ltrs	:	Liters
MCB	:	Miniature Circuit Break
Mm	:	Mili meter
mm	:	Millimeter
MOC	:	Material of Construction
NLT	:	Not Less Than
No.	:	Number
PLC	:	Programmable Logical Control
RMG	:	Rapid Mixer Granulator
V	:	Volt
WHO	:	World Health Organization



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR RAPID MIXER GRANULATOR**

**17.0 PROTOCOL POST -APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			