



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR RAPID MIXER GRANULATOR

Department: Quality Assurance	FAT No.:
Title: Factory Acceptance Test for Rapid Mixer Granulator	Effective Date:
Supersedes: Nil	Review Date:

**FACTORY ACCEPTANCE TEST
FOR
RAPID MIXER GRANULATOR**



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1.0 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 INTRODUCTION:

- The objective of this protocol is to confirm that the machine RMG manufactured by, at their Works in is in line with the specifications as desired by the customer.
- The objective of this Factory Acceptance Test is to verify that the equipment has been built & engineered according to the design specification and as a result approves the equipment for shipping to site. Handover will be following completion of successful site acceptance test.

3.0 SCOPE

3.1 The scope of this protocol is limited to the Factory Acceptance Test of RMG.

3.2 Any auxiliary equipment supporting this machine, required along with the machine, for its effective overall performance shall not be tested in this protocol. Any such auxiliary equipment, if present, shall be tested separately.

4.0 RESPONSIBILITY

The Qualification group comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this protocol:

Departments	Responsibilities
Quality Assurance	<ul style="list-style-type: none">• Preparation, review, approval and compilation of the FAT Document.• Co-ordination with Production and Engineering to carryout activity.
Production	<ul style="list-style-type: none">• Review of FAT Document.
Engineering	<ul style="list-style-type: none">• Review of FAT Document.• To co-ordinate and support FAT Activity.



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5.0 VERIFICATION OF TECHNICAL SPECIFICATIONS OF SUB-COMPONENTS & BOUGHT OUT ITEMS.

S.No.	Design/Component	Specification	Observation	Remark
1.	Machine type	RMG		
2.	Model		
3.	Application	Dry and wet mixing.		
4.	Features	Closed material transfer system		
		Powder loading with inline sifter by vacuum transfer system.		
		Powder unloading through Cone mill at discharge and materials direct transfer to Bowl of FBD and suction by FBD Blower.		
5.	Gross Volume in liters	600 Liters		
6.	Working Volume in Liters	500 Liters		
7.	Working Volume in Kg	250 Kg		
8.	Main Motor (HP)	40/50 HP Dual motor capacity		
9.	Main Impeller Speed	65 & 130 RPM Dual		
10.	Chopper Motor (HP)	5/7.5 HP, 50 Hz.		
11.	Chopper Blade Speed	1400 & 2800 RPM- Dual Speed.		
12.	Inline Cone Mill Motor	3 HP / 2.25 kw/3 Phase		
13.	Inline Cone Mill Speed	50 to 1440 RPM by VFD		
14.	Air purging System	Provided with 0.1 Micron filtration		
15.	Product Contact Parts/ Finish	SS 316 / Mirror polished		
16.	Electric controls panel	PLC Controls with Touch screen panel		
		3 Level Pass word.		
		Product wise parameter –Recipe management.		



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S.No.	Design/Component	Specification	Observation	Remark
		Selection Auto mode & Manual mode		
		On-Off Function		
		Auto process cycle for dry mixing time/ binder adding/ wet mixing granulation.		
		Auto fast and slow speed for mixing & granulation. Complete Process cycle controls on time by PLC.		
		Complete Process cycle controls on Ampere by PLC		
		Auto pneumatic sealing of top lid & discharge gate.		
		Auto air purging system on/off.		
		Auto discharge when process completed.		
		Cone mill speed set/actual.		
		Main Isolate switch.		
		Emergency Stop Switch.		
		MCB, Contactor, Relay, Controls relay & SMPS.		
17.	Documents	Machine Instruction manual with assembly drawings, parts list and electric wiring diagram.		
		Validation documents for DQ,FAT,IQ,SAT,OQ		
		Test certificate & MOC Certificate.		
18.	Require Utilities	Electric Power: 45.225kw/3 phase/415V/50Hz.		
	Steam	Nil		
	Compressed air	15 CFM		
	D.M. water	Nil.		
	Hot water	For washing required.		



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S.No.	Design/Component	Specification	Observation	Remark
	Plain water	For washing required.		
	D.M. water	For washing required.		

6.0 VERIFICATION OF MATERIAL OF CONSTRUCTION CERTIFICATES

S.No.	Component	MOC	Observation	Remarks
1.	Product Container	SS 316		
2.	Non contact part	SS 304		
3.	Bottom Chamber	SS 316		
4.	Main Body	SS 304		
5.	Rubber Seal	Rubber		



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7.0 VERIFICATION OF SAFETY FEATURES

S.No.	Features	Observation	Remarks
1.	Safety Interlocks for top lid.		
2.	Safety Interlocks for discharge gate open/closed.		
3.	Safety Interlocks for discharge housing open/closed.		
4.	Safety inter lock Air purging system		
5.	Inter lock compressed air pressure.		
6.	Inter lock for discharge pipe connected to transfer materials FBD.		
7.	Auto shutoff when process time OR Ampere set value achieved.		
8.	Overload relay controls.		
9.	Emergency stop.		
10.	Auto stop when sets time achieved.		



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8.0 VERIFICATION OF TEST/CALIBRATION CERTIFICATES

S.No.	Component	Status	Observation	Remarks
1.	Main Drive Motor	Test Certificate		
2.	Product contact part	Test Certificate		
3.	Non contact part	Test Certificate		
4.	Electrical drawing	Should be available		
5.	GA Drawing	Should be available		
6.	P & ID Drawing	Should be available		

9.0 VERIFICATION OF SURFACE FINISH

S.No.	Component	Surface Finish- Mirror/ Matt	Observation	Remarks
1.	Product contact part	Mirror		
2.	Non product contact part	Matt		



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11.0 SUGGESTIONS / MODIFICATIONS

S.No.	SUGGESTION FROM..... (IF ANY)	MANUFACTURER'S ACCEPTANCE
1.		
2.		
3.		
4.		
5.		

12.0 ABBREVIATIONS

Acronym	Definition
OSD	Oral solid dosage form
QA	Quality Assurance
FAT	Factory acceptance test
FBD	Fluidized bed dryer
HMI	Human machine interface
PLC	Programmable logical control
A.C.	Alternating current
HP	Horse power
Kw	Kilo-watt
cfm	Cubic feet per minute
VFD	Variable frequency drive
MCB	Miniature circuit breaker
PO	Purchase order
EC	European commission
V	Volt
Hz	Hertz
NA	Not applicable
EU	European union
cGMP	Current Good Manufacturing Practice
GMP	Good Manufacturing Practices



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13.0 POST APPROVAL

Name	Designation	Department	Signature

Name	Designation	Department	Signature