

Formulation, Research and Development Department

Pharma De	STANDARD OPERATING PROCEDUR	E			
Department: Formulation, Research and Development  SOP No.:					
Title: Op	eration and Cleaning of Rapid Mixer Granulator (Saral)	Effective Date:			
Supersed	es: Nil	Review Date:			
Issue Dat	e:	Page No.:			
1.0					
1.0	<b>OBJECTIVE:</b> To lay down the procedure for Operation and Cleaning of Rap	oid Mixer Granulator.			
2.0	SCOPE:				
	This SOP is applicable to Formulations Research and Develop	oment.			
3.0	RESPONSIBILITY:				
3.1	Executive – FR&D for operation and cleaning.				
3.2	Group Leader – FR&D will ensure the maintenance.				
3.3	Head – FR&D for implementation and compliance.				
4.0	<b>DEFINITION(s):</b>				
	Not Applicable				
5.0	PROCEDURE:				
5.1	PRECAUTIONS:				
5.1.1	Three different mixer bowls of 3-, 5- and 10-liters capacity a from the main frame.	are available, which can be detached			
5.1.2	While changing bowl, take care to see that the main impel bowl. So rotate the blade manually. If the bowl fixing bolts a may touch the bottom of the bowl.				
5.1.3	Ensure chopper blade is fixed properly by a bolt on the chopper	er shaft.			
5.1.4	Ensure that the main impeller is locked properly by tighten impeller.	ing the conical cap above the main			
5.1.5	Ensure by manually rotating the main impeller, that there is r face of discharge piston when in closed position.	no contact between the blade and the			
5.2	Pre setup				
5.2.1	Visually inspect the machine and the room for cleanliness.				
5.2.2	Ensure that the previous product's remaining are completely r				
5.2.3	Remove the clean equipment tag and tear it off after confirming	ng the details of the label.			
5.2.4	Put the equipment status label on the machine.				
5.3	Set up				
5.3.1	Select the bowl as per the batch size and fix it with the help of	f two wing nuts with the main frame.			
5.3.2	Tighten the mixer bowl with the help of the wing nuts.				
5.3.3	Now fix the impeller corresponding to the bowl. Place the co	nical cap and tighten it by turning it			
5 2 A	in clockwise direction.	- Commercial distribution			
5.3.4	Ensure that the compressed air connection is made to the mair	i frame and the discharge outlet.			
5.3.5	Ensure that compressed air should be between 4 to 8 kg/cm <sup>2</sup> .				



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5.3.6	Switch on the main power supply and ensure that the chopper motor	and main motor indicators					
3.3.0	are working properly.	and main motor mulcators					
5.3.7	Ensure that the discharge flap is working properly. Now switch off	the power supply till the					
	equipment is used for operation						
5.4	Operating Instructions						
5.4.1	Switch on the main power supply.						
5.4.2	Place a empty bowl below the discharge outlet and ensure that the	discharge flap is in closed					
- 1 a	position. Then charge the materials into the mixer bowl.						
5.4.3	Close the lid and tighten the clamp.						
5.4.4	Start dry mixing by pressing ON button (The rpm of the main	1					
	multiplying the reading shown on the display by 6. For eg. If the fi impeller drive is showing 40 Hz. then the impeller speed is 6 X 40 =	•					
	by a black knob present above the impeller display.	240). The speed can be set					
5.4.5	impeller is running at slow						
5.4.5 Charge the granulating fluid or paste using special hopper while main impeller is running speed.							
5.4.6	here is a variable drive and						
the speed can be increased or decreased by a knob present above chopper display. The rpm of							
	chopper is calculated by multiplying the reading shown on chopper disp	play by 60).					
5.4.7	Stop the mixer and chopper.						
5.4.8	Open the lid and observe the granules for consistency and press "Discl	harge" button to unload the					
	material into the bowl if the granulation is completed.						
5.4.9	Open the lid and scrap the material.						
5.4.10	Close the lid and switch on the mixer.						
5.4.11 Remove the scrapped material.							
5.4.12 <b>5.5</b>	Switch off the mixer.  Shut down						
5.5.1	Close the compressed air supply valve.						
5.5.2	Switch off the main power supply.						
5.5.3 Put 'To be cleaned' label on the mixer.							
5.6							
5.6.1 Remove the impeller by turning the conical cap in anticlockwise direction. Remove the							
	from the chopper shaft by loosening the bolt nut.	11					
5.6.2	Remove the mixer bowl and take to wash area. Clean the inside of the	bowl, impeller and chopper					
	with tap water and finally with DM water.						
5.6.3	Wipe all the parts of the machine including the main frame with a dry c						
5.6.4	Ensure that all the parts are cleaned properly and place 'Cleaned' label	on the mixer.					
6.0	REFERENCE(s):						
3.0	Not Applicable						
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#### 7.0 ABBREVIATION(s):

Abbreviation	Full Description					
SOP	Standard Operating Procedure					
FR&D	Formulations Research and Development					
DM	Demineralized					
kg	Kilogram					

### 8.0 FLOWCHART(s):

Not Applicable

#### 9.0 ANNEXURE(s):

Annexure No.	Details/Title of Annexure	Format No. (Current version)
Annexure 01	Equipment log sheet	



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	Annexure 01				
		<b>Equipment Log</b>	g Sheet		
<b>Equipment Name</b>	:				
Equipment No.	:				
Location	:				
Month & Year	:				

Date	Product	Batch No.	Lot No.	Start Time	Stop Time	Cleaning Machine break down		Operator	Checked by	Remarks		
						From	To	From	To			