



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning & Operation of Rapid Mixer Granulator (100 L)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

- 1.1 To lay down a procedure for cleaning and operation of Cleaning and Operation of Rapid Mixer Granulator 100 L (Make: Anchor Mark).

2.0 SCOPE:

- 2.1 This procedure is applicable to the cleaning and operation of Cleaning and Operation of Rapid Mixer Granulator 100 L (Make: Anchor Mark) in the production area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation
3.2 Production Officer/Executive: Checking cleaning and operation
3.3 Head Production : SOP Compliance
3.4 IPQA Person : Line Clearance

3.5

4.0 DEFINITION (S):

- 4.1 NA
4.2

5.0 PROCEDURE:

- 5.1 **“TYPE A” CLEANING- Changeover from one batch to next batch of the same product and same potency and of similar product with ascending potency.**

- 5.1.1 Remove “UNDER PROCESS” label and affix dully filled “TO BE CLEANED” label to the machine.
5.1.2 Enter the cleaning start time equipment usage and cleaning log sheet as per SOP.
5.1.3 Ensure that the main power supply is switched OFF.
5.1.4 Scrub the deposited material of the RMG from inside with the help of S.S. spatula.
5.1.5 Clean the inner and outer side of the RMG with the help of dry lint free duster.
5.1.6 Clean the control panel and attached utility pendent with dry lint free cloth.
5.1.7 Affix dully filled status label on RMG as “CLEANED” with date and signature of Production Officer verified by QA officer.
5.1.8 Record the cleaning completion time in equipment usage log sheet as per SOP.

- 5.2 **“TYPE B” CLEANING: Changeover of product with different actives / colour / descending potency or after maintenance of contact parts.**

- 5.2.1 Remove “UNDER PROCESS” label and affix dully filled “TO BE CLEANED” label to the machine.



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- 5.2.2 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.2.3 Operate the touch screen of the RMG to close the discharge port. Open the lid and fill 60 liters of purified water. Close the lid and run the RMG at slow speed with the slow chopper ON for 5 minutes.
- 5.2.4 Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.
- 5.2.5 Open all the clamps, remove all the gaskets and clean with 5-7 liters of purified water.
- 5.2.6 Put off the mains.
- 5.2.7 Remove lid and loading port gasket clamp, RMG filter bag screw. Apply 25 liters of purified water to inner and outer surface and scrub the machine with nylon scrubber.
- 5.2.8 Clean the RMG filter bag with 40 liters of purified water and dry it along with the FBD finger bags.
- 5.2.9 After scrubbing clean the parts with 30 liters of purified water.
- 5.2.10 Clean the RMG, chopper motor cover, fixed lifter outer body, fixed lifter base with wet cloth dipped in purified water.
- 5.2.11 Open the lid of the RMG and remove the inverted cone shaped dome by turning the handles in clockwise direction. Remove the agitator by pulling it up wards with the help of handles provided. Remove the agitator blades with the help of a Teflon hammer.
- 5.2.12 Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.
- 5.2.13 Clean the agitator blade and chopper blade with 30 liters of purified water by scrubbing with nylon scrubber.
- 5.2.14 Clean the agitator blade and chopper blade with 30 liters of purified water
- 5.2.15 Scrub the inside of the RMG with nylon scrubber using 40 liters of purified water.
- 5.2.16 Scrub the outside, lid and platform of RMG with a nylon scrubber using 40 liters of purified water.
- 5.2.17 Unscrew the panel covering on the front side and the side covers. Dry clean the machine from inside using vacuum cleaner and dry lint free duster. Clean underneath the rapid mixer granulator. Clean the side covers by using 30 liters of purified water with nylon scrubber. Fit the panel covering and side covers back in place.
- 5.2.18 Wash the discharge port by scrubbing the area with a nylon scrubber using 60 liters of purified water.
- 5.2.19 Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 40 liters of purified water.
- 5.2.20 Reassemble the agitator blades, dome and chopper assembly in reverse order of dismantling.
- 5.2.21 Ensure that area is cleaned as per SOP.



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- 5.2.22 Wipe out the all parts of RMG with a clean dry lint free duster. Wipe with 70% v/v IPA and cover the discharge port with help of a polyethylene bag. Put on the mains and operate the touch screen to close the discharge valve and top lid.
- 5.2.23 Clean the control panel, limit switch, railings and the attached utility pendent by using a dry lint free cloth.
- 5.2.24 Replace the “TO BE CLEANED” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.25 Record the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.26 Record the cleaning activity in Annexure-I.

5.3 Frequency

- 5.3.1 Type ‘A’ cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than seven days then follow the procedure of type – B cleaning.
- 5.3.2 Type ‘B’ cleaning is applicable in case of change over of product with different actives / color / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.
- 5.3.3 Cleaning (Dedusting of machine with vacuum cleaner and dry lint free cloth) is applicable in case of at the end of working day.

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine “before use”, with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the “CLEANED” label again. Record the activity in equipment usage log sheet as per SOP.

5.4 OPERATION:

5.4.1 Machine setting

- 5.4.1.1 Ensure that the equipment and area is cleaned. Affix ‘UNDER PROCESS’ label dully filled and signed on the equipment and record the observation in the Equipment Usage Log Sheet as per SOP.
- 5.4.1.2 Ensure that the compressed air and main electric supply is ‘ON’ from service Area and Ensure discharge valve is closed.
- 5.4.1.3 Check the integrity (Intactness) of all gaskets of RMG before and after use. If gasket found damaged, it shall be handled through unplanned deviation report. (Reference SOP).
- 5.4.1.4 Turn Control ‘ON/OFF’ switch on control panel to ‘ON’ position. Opening screen will open on MMI.



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5.4.1.5 Ensure that Compressed air pressure on pressure gauge is approximately 4 Bar. If not, adjust by turning Lock knob in clockwise direction to increase the Pressure and anticlockwise to decrease the pressure.

5.4.2 **Recipe Edit / Load**

5.4.3 Switch on the power supply by turning the selector switch in clockwise direction.

5.4.4 Welcome screen will open, in welcome screen LOGIN, LOGOUT, and MAIN MENU keys will be shown..

5.4.4.1 Touch 'login' on MMI. Keypad screen will open. Enter correct password.

5.4.4.2 Touch on Main menu key main menu screen will open.

5.4.4.3 In main menu screen following keys will be shown.

AUTO MODE	RECIPE
MANUAL MODE	ADMIN
DISCHARGE MODE	PLC I/O
HOME	ALARM

5.4.4.4 Click on RECIPE key following contents will be shown.

PRODUCT NAME----
EQUIPMENT ID----
BATCH NO----
LOT NO----
USER----

SAVE	DELETE	LOAD	RECIPE PAGE 1
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5.4.4.5 If recipe is already saved click on LOAD key and select the recipe .

5.4.4.6 After recipe selection change the batch number, user name and lot number.

5.4.4.7 For new recipe enter the information and click on save key a popup will be shown for save as new or change existing, click on save as new. New recipe will be created .

5.4.4.8 Click on RECIPE PAGE 1 following parameters will be shown.

End point current-----

End point current 2-----



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
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Dry mixing	Binder addition	Gr 1	Binder addition -2	Gr 2
Additional Qty	Gr 3	Gr 4	Gr 5	Gr 6
	HOME		HEATING	

5.4.4.9 Click on dry mixing key and change the impeller and chopper speed and set the time in set time column as per respective BMR .

5.4.4.10 For remaining cycle follow same procedure as 5.4.4.10.

5.4.4.11 For deletion of existing recipe click on delete key, list of saved recipe will appear, select the recipe and delete.

5.5 Auto Mode Operation

5.5.1 Click on auto mode key following contents will show on the screen . set time, actual time, impeller set RPM, actual RPM, actual current,speed, chopper set RPM, Actual RPM,Actual current, Speed. End point current, End point current -2.

AUTO ENABLE	START	STOP	CYCLE RESET
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5.5.2 Set the print page in printer.

5.5.3 Click on auto enable key.Colour of key becomes green.

5.5.4 Click on start key machine will start .

5.5.5 Machine will stop after each cycle time completion. And ask to continue for next cycle. If next cycle required , click on start key to start the machine for next cycle.

5.5.6 If require stop the machine by click on stop key.

5.5.7 After achieving of end point current a popup generated as end point current achieved .

Note : 1) In each run the actual time on print shown either equal or 1 to 2 sec less or more so that the time limit of each run shall be ± 2 sec.

2) Each zero time cycle will be considered as 1-2 sec so that total time of granulation will be total set time plus each zero cycle considered as ± 2 sec.

3) Before loading of material ensure that the discharge port is closed.

5.5.8 After completion of all cycle a message display to enable the cycle click on enable .

5.6 Manual Mode Operation

5.6.1 Click on manual mode to operate the machine in manual mode. Manual screen will open.



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5.6.2 Set the parameter as set time , impeller speed (slow/fast) , chopper speed (slow/fast/off) by click on slow or fast. impeller RPM by default set as 75 for slow speed and 150 for fast speed and same for chopper 1440 for slow speed and 2880 for fast speed.

5.6.3 Following key will shown on HMI for operation of manual mode.

MANUAL MODE	START	STOP	HOME
DISABLE /ENABLE			

5.6.4 Enable the manual mode by click on manual mode disable enable key.

5.6.5 Start the machine by click on start key.

5.7 Discharge Mode Operation

5.7.1 For discharge mode operation mode operation click on discharge mode key, discharge mode screen will open.

5.7.2 Following contents will shown on discharge cycle.

IMPELLER SPEED	
CHOPPER SPEED	

IMPELLER START	CHOPPER START	IMPELLER INCH
DISCHARGE MODE	DISCHARGE PORT	DISCHARGE PORT
DISABLE/ENABLE	OPEN	CLOSE

5.7.3 Enable the discharge mode by click on discharge mode disable key.

5.7.4 Set the impeller RPM and chopper RPM as per respective BMR.

5.7.5 Open the discharge port by click on discharge port open key.


5.7.6 Start the impeller and chopper by click on impeller start and chopper start key.

5.8 Jacketed Operation of RMG

5.8.1 Touch on "RECIPE" the recipe screen will open.

End point current-----

End point current 2-----

Dry mixing	Binder addition	Gr 1	Binder addition -2	Gr2
Additional Qty	Gr3	Gr4	Gr5	Gr6
	HOME		HEATING	



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5.8.2 Touch on heating key following screen will open.

Bowl temp set Actual

**HEATING
ON/OFF**

BACK

HOME

5.8.3 Set the temperature as per respective BMR.

5.8.4 Touch on heating ON/OFF key , the steam valve will open .

5.8.5 Set the parameter as impeller speed chopper speed and time in auto or manual mode.

5.8.6 Select auto or manual mode to start the machine .

5.8.6.1 After completion of activity OFF the heating by click on Heating on off key.

5.8.6.2 For cooling open the inlet of chilled water supply after lowering of the temperature close the inlet of chilled water.

NOTE: Ensure that physical valve of inlet and outlet steam/condense is open prior to select from machine HMI.

6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 No. : Number
- 6.4 S.S. : Stainless Steel.
- 6.5 V/V : Volume / Volume
- 6.6 RMG : Rapid Mixer Granulator
- 6.7 MMI : Man Machine Interface
- 6.8 BMR : Batch manufacturing record

7.0 REFERENCE (S)

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: Cleaning of production area.
- 7.3 SOP: Status Labeling
- 7.4 SOP: Operation of Vacuum cleaner.



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8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure- I	Cleaning Checklist		Log book

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (S):** Production department (01), Quality Assurance (01).

9.3 **Reference Copy (S):** Production department (01).

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (S) For revision	Details of revision	Effective Date



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ANNEXURE I

CLEANING CHECKLIST OF RMG (Capacity 100 Liters)

Name of the Equipment		Rapid Mixer Granulator (Capacity 100 Liters)	
Equipment ID No.			
Previous product			
Batch No.		Date	
S.No.	Activity	Activity Performed	
1.	Operate the touch screen of the RMG to close the discharge port. Open the lid and fill 60 liters of purified water. Close the lid and run the RMG at slow speed with the slow chopper ON for 5 minutes.		
2.	Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.		
3.	Open all the clamps, remove all the gaskets and clean with 5-7 liters of purified water.		
4.	Put off the mains.		
5.	Remove lid and loading port gasket clamp, RMG filter bag screw. Apply 25 liters of purified water to inner and outer surface and scrub the machine with nylon scrubber.		
6.	Clean the RMG filter bag with 40 liters of purified water and dry it along with the FBD finger bags.		
7.	After scrubbing clean the parts with 30 liters of purified water.		
8.	Clean the RMG, chopper motor cover, fixed lifter outer body, fixed lifter base with wet cloth dipped in purified water.		
9.	Open the lid of the RMG and remove the inverted cone shaped dome by turning the handles in clockwise direction. Remove the agitator by pulling it up wards with the help of handles provided. Remove the agitator blades with the help of a Teflon hammer.		
10.	Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.		
11.	Clean the agitator blade and chopper blade with 30 liters of purified water by scrubbing with nylon scrubber.		
12.	Clean the agitator blade and chopper blade with 30 liters of purified water		
13.	Scrub the inside of the RMG with nylon scrubber using 40 liters of purified water.		



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S.No.	Activity	Activity Performed
14.	Scrub the outside, lid and platform of RMG with a nylon scrubber using 40 liters of purified water.	
15.	Unscrew the panel covering on the front side and the side covers. Dry clean the machine from inside using vacuum cleaner and dry lint free duster. Clean underneath the rapid mixer granulator. Clean the side covers by using 30 liters of purified water with nylon scrubber. Fit the panel covering and side covers back in place.	
16.	Wash the discharge port by scrubbing the area with a nylon scrubber using 60 liters of purified water.	
17.	Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 40 liters of purified water.	
18.	Reassemble the agitator blades, dome and chopper assembly in reverse order of dismantling	
19.	Ensure that area is cleaned as per SOP.	
20.	Wipe out the all parts of RMG with a clean dry lint free duster. Wipe with 70%v/v IPA and cover the discharge port with help of a polyethylene bag. Put on the mains and operate the touch screen to close the discharge valve and top lid.	
21.	Clean the control panel, limit switch, railings and the attached utility pendent by using a dry lint free cloth.	
22.	Replace the "TO BE CLEANED" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.	
23.	Check the integrity (intactness) of all the gaskets.	

Note: Put '√' mark if activity performed and put 'X' if activity not performed.

Checked By (Prod.)
Sign/date

Verified By (QA)
Sign/date