



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 Liters).

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation procedure of Rapid Mixer Granulator (Capacity 25 Liters), 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

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over 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 in 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 SS Spatula.
5.1.5 Clean the inner and outer side of the RMG with the help of dry lint free duster.
5.1.6 Affix dully filled status label on RMG as "CLEANED" with date and signature of Production Officer and verified by QA officer.
5.1.7 Record the cleaning completion time in equipment usage log sheet as per SOP.

5.2. "TYPE B" CLEANING:

Changeover of product with different actives/color/descending potency or after maintenance of contact parts.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.1 Remove "UNDER PROCESS" label and affix dully-filled "TO BE CLEANED" label to the machine.
- 5.2.2 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.2.3 Open all the clamps, remove all the gaskets and clean with 5-10 liters of purified water.
- 5.2.4 Cover the control panel with poly bag to avoid water entry in to them.
- 5.2.5 Operate the RMG to close the discharge port. Open the lid and fill 10 liters of purified water, Close the lid and run the RMG at slow speed for 5 minutes with the slow chopper 'ON'.
- 5.2.6 Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.
- 5.2.7 Put 'OFF' the mains.
- 5.2.8 Remove lid and loading port gasket clamp, RMG finger bag screw. Apply 10 liters of purified water to inner and outer surface and scrub the machine with nylon scrubber.
- 5.2.9 Clean the RMG filter bag with 2-5 liter of purified water and dry it along with the FBD finger bags.
- 5.2.10 After scrubbing clean the parts with 10-12 liters of purified water.
- 5.2.11 Clean the RMG; chopper motor cover with wet lint free cloth dipped in purified water.
- 5.2.12 Clean the control panel, limit switches, and the utility cables by using a dry lint free cloth.
- 5.2.13 Open the lid of the RMG and remove the inverted cone shaped dome by unscrew the agitator. Remove the agitator by pulling it up wards.
- 5.2.14 Open and remove the nozzle plate, clean it with 5-6 liters of purified water and visually check the integrity of the gasket and then reassemble.
- 5.2.15 Clean the purging air hole with purified water.
- 5.2.16 Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.
- 5.2.17 Clean the agitator blade and chopper blade 10-12 liters of purified water by scrubbing with nylon scrubber.
- 5.2.18 Clean the agitator blade and chopper blade with 15 to 20 liters of purified water
- 5.2.19 Scrub the inside of the RMG with nylon scrubber using 15 – 20 liters of purified water.
- 5.2.20 Scrub the outside, lid and platform of RMG with a nylon scrubber using purified water.
- 5.2.21 Dry-clean the machine from inside using dry lint free duster. Clean underneath the rapid mixer granulator. Clean the side cover by using purified water with nylon scrubber.
- 5.2.22 Open the discharge port by unscrews the bolt in anticlockwise direction.
- 5.2.23 Wash the discharge port by scrubbing the area with a nylon scrubber using 10-15 liters of purified water.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.24 Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 10-20 liters of purified water.
- 5.2.25 Reassemble the agitator and chopper assembly in reverse order of dismantling.
- 5.2.26 Ensure that area is cleaned as per SOP.
- 5.2.27 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 to close the discharge valve.
- 5.2.28 Replace the “TO BE CLEANED” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.29 Record the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.30 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 a week then follow the procedure of type – B cleaning.
- 5.3.2 Type ‘B’ cleaning is applicable in case of changeover 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 as per SOP.

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 Turn Control ‘ON/OFF’ switch on control panel to ‘ON’ position.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4.1.4 Set the purging air requirement with the regulator controller. If purging air dropped, the displayed value shows in red and machine not start. When purging air resume, the displayed value shows in green and machine is ready to use.

5.4.1.5 Check the integrity (intactness) of all gaskets before and after use. If gasket found damage (not OK), it is handled through the Un Deviation procedure as per SOP.

5.4.2 Manual Mode Operation:

5.4.2.1 Operate the RMG manually with the help of pressing 'START' and 'STOP' buttons provided on the control panel for agitator and chopper respectively.

5.4.2.2 Set the time of agitator motor running and chopper motor running with the help of pressing the respective buttons. (Time setting range from 0 to 999 minutes)

5.4.2.3 Total machine running time shows on the 'TIME TOTALISER' display unit.

5.4.2.4 At the time of granulation the ampere reading of the AGITATOR and CHOPPER motors shows on the 'AGITATOR MOTOR CURRENT' and 'CHOPPER MOTOR CURRENT' unit on the control panel.

5.4.2.5 Discharge is pneumatically operated and CLOSE and OPEN with the help of turn the respective switch on the control panel on CLOSE and OPEN side.

5.4.2.6 Speed of the agitator motor control with the help of AGITATOR MOTOR speed controller. By turning Anticlockwise direction the speed of motor decreases and by turning Clockwise direction, the speed of motor increases. It is ranges from 51 to 300 RPM, above the 300 RPM it is shows the "h" (indicates high motor speed).

5.4.2.7 Speed of the chopper motor control with the help of CHOPPER MOTOR speed controller. By turning Anticlockwise direction the speed of motor decreases and by turning Clockwise direction, the speed of motor increases. It is ranges from min. 1710 to max. 2908 RPM.



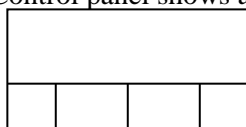
PHARMA DEVILS

PRODUCTION DEPARTMENT

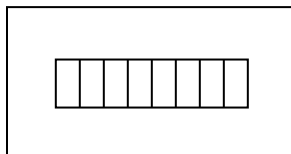
STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

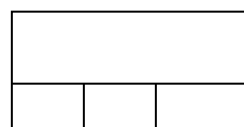
5.4.2.8 Control panel shows as follows-



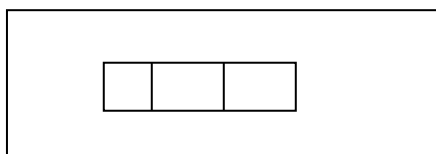
TIMER FOR
AGITATOR



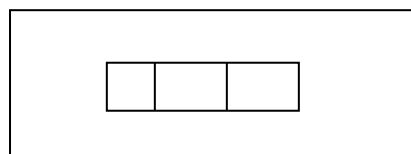
TIMER
TOTALISER



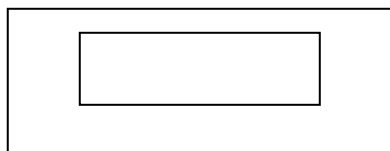
TIMER FOR
CHOPPER



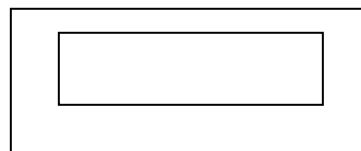
AGITATOR MOTOR
CURRENT



CHOPPER MOTOR
CURRENT



STOP START



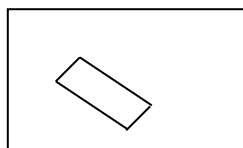
STOP START



AGITATOR
MOTOR



DISCHARGE
CLOSE OPEN



CHOPPER
MOTOR



CONTROL PANEL

- 5.4.2.9 After achieving the required Amp. Load and dough mass, stop the machine.
- 5.4.2.10 Turn 'OPEN' to open the discharge and collect the material in the FBD bowl.
- 5.4.2.11 After that turn 'OFF' the control panel and affix 'TO BE CLEANED' label dully filled and signed on the equipment.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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
- 6.6 FBD : Fluid Bed Dryer

7.0 REFERENCES (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.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	CLEANING CHECKLIST OF RMG (Capacity 25 Liters) (Gansons)		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (s):** Production department (1) / Quality Assurance (1)
- 9.3 **Reference Copy (s) :** Production department (1)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details Of Revision	Effective Date
1.	00	NA	New SOP	NA	NA



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I CLEANING CHECKLIST OF RMG (Capacity 25 Liters) (Gansons)

Name of the Equipment		RMG (Capacity 25 Liters) (Gansons)	
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity Performed
1.	Cover the control panel with poly bag to avoid water entry in to them.	
2.	Operate the RMG to close the discharge port. Open the lid and fill 10 liters of purified	
3.	Remove all the gaskets and clean with 5-10 liters of purified water.	
4.	Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.	
5.	Put 'OFF' the mains.	
6.	Remove lid and loading port gasket clamp, RMG finger bag screw. Apply 10 liters of purified water to inner and outer surface and scrub the machine with nylon scrubber.	
7.	Clean the RMG filter bag with 2-5 liter of purified water and dry it along with the FBD finger bags.	
8.	After scrubbing clean the parts with 10-12 liters of purified water.	
9.	Clean the RMG; chopper motor cover with wet lint free cloth dipped in purified water.	
10.	Clean the control panel, limit switches, and the utility cables by using a dry lint free cloth.	
11.	Open the lid of the RMG and remove the inverted cone shaped dome by unscrew the agitator. Remove the agitator by pulling it up wards.	
12.	Open and remove the nozzle plate, clean it with 5-6 liters of purified water and visually check the integrity of the gasket and then reassemble.	
13.	Clean the purging air hole with purified water.	
14.	Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.	
15.	Clean the agitator blade and chopper blade 10-12 liters of purified water by scrubbing with nylon scrubber.	
16.	Clean the agitator blade and chopper blade with 15 to 20 liters of purified water	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator (Capacity 25 liters)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

S.No.	Activity	Activity Performed
17.	Scrub the inside of the RMG with nylon scrubber using 15 – 20 liters of purified water.	
18.	Scrub the outside, lid and platform of RMG with a nylon scrubber using purified water.	
19.	Dry-clean the machine from inside using dry lint free duster. Clean underneath the rapid mixer granulator. Clean the side cover by using purified water with nylon scrubber.	
20.	Open the discharge port by unscrews the bolt in anticlockwise direction.	
21.	Wash the discharge port by scrubbing the area with a nylon scrubber using 10-15 liters of purified water.	
22.	Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 10-20 liters of purified water.	
23.	Reassemble the agitator and chopper assembly in reverse order of dismantling.	
24.	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 to close the discharge valve.	
25.	Replace the “TO BE CLEANED” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.	
26.	Check the integrity (intactness) of all the gaskets.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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