



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin

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 1200 Liters)

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation procedure of Rapid Mixer Granulator (Capacity 1200 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 with same color and flavor.**

5.1.1 Remove “UNDER PROCESS” label and affix dully filled “TO BE CLEANED” label to the machine as per SOP “Status labeling”

5.1.2 Remove “TO BE CLEANED” label and affix “UNDER CLEANING” label as per SOP “Status labeling”

5.1.3 Enter the cleaning start time equipment usage and cleaning log sheet as per SOP “Equipment Usage and cleaning log book”

5.1.4 Ensure that the main power supply is switched OFF.

5.1.5 Scrub the deposited material of the RMG from inside with the help of Teflon scraper.

5.1.6 Open the shroud and scrap the material from co- mill screen if used and shroud inner wall.

5.1.7 Clean the inner and outer side of the RMG with the help of dry lint free duster.



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Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.1.8 Affix dully filled “CLEANED” status label as per SOP “Status labeling” on RMG with date and signature of Production Officer verified by QA officer.
- 5.1.9 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.**
- 5.2.1 Remove “UNDER PROCESS” label and affix dully filled “TO BE CLEANED” label to the machine as per SOP “Status labeling”
- 5.2.2 Before start of cleaning activity remove “TO BE CLEANED” label and affix “UNDER CLEANING” label as per SOP “Status labeling”
- 5.2.3 Enter the cleaning start time equipment usage and cleaning log sheet as per SOP “Equipment usage and cleaning log book”
- 5.2.4 Touch ‘LOGIN’ ON MMI. Keypad screen shall open and ‘LOGIN’ to operator mode.
- 5.2.5 Touch ‘MODE SELECTION’ on MMI.
- 5.2.6 Touch ‘MANUAL’ on MMI. MANUAL main screen shall open. There are three content in manual mode “PNEUMATIC CONTROL” “MOTOR CONTROL” “WIP CONTROL”
- 5.2.7 In “PNEUMATIC CONTROL” touch the purging air to OPEN and touch discharge valve to CLOSE and fill with purified water upto chopper height (approx 500 liters of purified water). Close the charging port.
- 5.2.8 Touch “MOTOR CONTROL” and start impeller and chopper in slow speed for 5 minutes to remove the adhesive material.
- 5.2.9 Place a suitable container beneath the discharge port of the RMG. Click on Bypass to bypass the bowl and then Open the discharge valve and drain the wash water.
- 5.2.10 Open all the clamps and remove the gaskets of charging port, vent filter, view glass and clean with 5-10 liters of purified water using nylon scrubber.
- 5.2.11 Clean the filter bag housing and hose pipe with 40-50 liters of purified water using nylon scrubber.
- 5.2.12 Open the lid of RMG and remove the lid gasket and clean with 10-20 liters of purified water using nylon scrubber.
- 5.2.13 Remove the inverted cone shaped dome by turning the handles in anticlockwise direction.
- 5.2.14 Again touch MOTOR CONTROL and go to last screen and enable the lifting device.
- 5.2.15 Down the rope of lifter by push the manual controller and fit the nut of lifter rope with impeller.
- 5.2.16 Pulling the impeller upward by pushing the button of manual controller.



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Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.17 Dismantle the impeller and chopper and clean with 30-50 liters of purified water using high pressure jet cleaner.
- 5.2.18 Turn off the mains.
- 5.2.19 Apply 80-140 liters of purified water to inner and outer surface using high pressure jet cleaner and scrub the machine intermittently with nylon scrubber/Teflon scraper.
- 5.2.20 Clean the RMG filter bag as per SOP "Cleaning and utilization of FBD/FBP/RMG filter bag, Air Jet Micronizer filter bag".
- 5.2.21 Clean the cleaned parts with 2% sodium Lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.
- 5.2.22 After scrubbing clean the parts with 50-120 liters of purified water using high pressure jet cleaner.
- 5.2.23 Clean the chopper motor cover, fixed lifter outer body, fixed lifter base, railing and co-mill motor cover with wet cloth dipped in purified water.
- 5.2.24 Clean the control panel, limit switch, the utility cables by using a dry lint free cloth.
- 5.2.25 Scrub the inside of the RMG with nylon scrubber using 70-80 liters of purified water.
- 5.2.26 Scrub the outside, lid and platform of RMG with a nylon scrubber using 40-50 liters of purified water.
- 5.2.27 Wash the discharge port and discharge valve with 50-60 liters of purified water using high pressure jet cleaner and scrub intermittently with nylon scrubber
- 5.2.28 Dis-mental the shroud and scrub the deposited material from inner side of shroud and co-mill screen if used with 20-30 liters of purified water.
- 5.2.29 Rinse the agitator, chopper, discharge valve, inside lid, outside, shroud and platform of the RMG with 90-120 liters of purified water.
- 5.2.30 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 purified water with nylon scrubber. Fit the panel covering and side covers back in place.
- 5.2.31 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. Close the discharge valve and top lid.
- 5.2.32 Record the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.33 Ensure that area is cleaned as per SOP.
- 5.2.34 Replace the "UNDER CLEANING" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.



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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.35 Again turn on the PLC.
- 5.2.36 Reassemble the all dismantled assembly in reverse order of dismantling.
- 5.2.37 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 as per SOP.
- 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 as per SOP.

NOTE: If the machine is idle for 72 hours to 240 hours after B type cleaning, then wipe with 70% v/v IPA solution with the help of a lint free cloth and update the CLEANED status label with current date before use. If expire the cleaning validity (240 hrs or 10 days) after type B cleaning then type B cleaning shall be performed before use.

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
- 5.4.1.3 Check the integrity (intactness) of all gasket of RMG before and after use. If gasket found damaged, It shall be handled through unplanned deviation report.
- 5.4.1.4 Area and Ensure discharge valve is closed.
- 5.4.1.5 Turn Control 'ON/OFF' switch on control panel to 'ON' position. Opening screen shall open on MMI.
- 5.4.1.6 Ensure that Compressed air pressure on pressure gauge is approximately 6 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 and create new recipe:

- 5.4.2.1 There are three level password:



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PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Password level	Function accessibility
OPERATOR	All functions of MANUAL mode, ON START and STOP in auto mode
SUPERVISOR	All function of MANUAL mode, Recipe Load, Edit batch number. ON START and STOP in auto mode
MANAGER	All function of MANUAL mode. EDIT, SAVE, delete the Recipe, ON, START, STOP, CHANGE PASSWORD, in auto mode.

- 5.4.2.2 Touch 'LOGIN' ON MMI. Keypad screen shall open.
- 5.4.2.3 Enter correct user ID and password
- 5.4.2.4 Main menu screen shall open. Content of main menu is "WELCOME" "ALARM" "PRINT" "MODE SELECTION" "ADMINISTRATION". Touch 'MODE SELECTION' on MMI. Select auto mode.
- 5.4.2.5 Touch 'AUTO' on MMI. Auto operation main screen shall open. Touch 'RECIPE DICTIONERY' on MMI. Select any recipe and copy through copy touch.
- 5.4.2.6 Select the copied recipe then touch edit option on screen. Edit the recipe as new recipe. By touch on edit user can change the name of Recipe.
- 5.4.2.7 Download the edited recipe. Go back through back (←) arrow and edit the recipe parameter of all screens as per BMR requirement.
- 5.4.2.8 Edit recipe code, Batch no, product name, pre mixing time, final mixing time, delay time, binding time, granulation 1 time as per BMR and save by touch on "SAVE".
- 5.4.2.9 Touch 'DOWN' on MMI. Recipe Parameter 2/5 screen shall open.
- 5.4.2.10 Edit granulation 2 times, granulation 3 time Premixing impeller (RPM), premixing chopper delay, premixing chopper (RPM) final mixing impeller (RPM), final mixing chopper delay, as per respective BMR.
- 5.4.2.11 Touch 'DOWN' on MMI. Recipe Parameter 3/5 screen shall open
- 5.4.2.12 Edit final mixing chopper (RPM), Binder addition impeller (RPM), Binder addition chopper delay, Binder addition chopper (RPM), granulation 1 impeller (RPM), Granulation 1 chopper delay, Granulation 1 chopper (RPM), Granulation 2 impeller (RPM), as per respective BMR. And save by touch on "SAVE".
- 5.4.2.13 Touch 'DOWN' on MMI. Recipe Parameter 4/5 screen shall open



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.2.14 Edit Granulation 2 chopper delay time, Granulation 2 Chopper (RPM), Granulation 3 impeller (RPM), Granulation 3 chopper (RPM) Discharge impeller (RPM), Discharge chopper delay time, Discharge chopper (RPM), as per respective BMR and save by touch on "SAVE".
- 5.4.2.15 Touch 'DOWN' on MMI. Recipe Parameter 4/5 screen shall open
- 5.4.2.16 Edit End point current (AMP), Wet mill motor (RPM).and save by touch on "SAVE"
- 5.4.2.17 Set the bowl temperature set point in stem jacketed bowl as per BPR parameter.
- 5.4.2.18 For start of operation touch on auto cycle and start the operation by touch "START"
- 5.4.2.19 To load already exist recipe touch "RECIPE DIRECTORY" on MMI. Select Recipe and download the recipe. By click on "DOIWNLOAD"

5.5 Auto Mode Operation

- 5.5.1 Touch on "MODE SELECTION" and select "AUTO" mode.
- 5.5.2 Touch on "PROCESS PARAMETER" and match the parameter with BMR.
- 5.5.3 Touch 'AUTO CYCLE' on MMI. Auto cycle main screen shall open.
- 5.5.4 Touch "RESET" to reset the parameter.
- 5.5.5 Touch "START" to start the cycle and go to next screen through '→' to see the running cycle.
- 5.5.6 After Completion of All Steps a message display on MMI granulation cycle completed do you want to start discharge cycle. If yes touch "YES" and start the cycle.
- 5.5.7 Before unloading ensures that the bowl is available at place.

5.6 Manual Mode Operation:

- 5.6.1 Touch on "MODE SELECTION" Select manual mode.
- 5.6.2 Touch on "PNEUMATIC CONTROL" and close the discharge valve.
- 5.6.3 Touch on "PURGING" and ON the purging air.
- 5.6.4 Touch "MOTOR CONTROL" and enter time and rpm of impeller, chopper and co-mill, touch start to impeller and chopper.
- 5.6.5 At the end of operation touch 'MODE OPERATION' on MMI. Mode selection screen shall open.
- 5.6.6 Touch 'MAIN MENU' on MMI. Main menu screen shall open.
- 5.6.7 Touch 'WELCOME' on MMI. Opening screen shall open.
- 5.6.8 Turn 'OFF' the control panel and affix 'TO BE CLEANED' labels dully filled and signed on the equipment.
- 5.6.9 In case of "AUTO" mode failure during batch processing, machine can be run in "MANUAL" mode to complete the batch by intimating to QA and Engineering department.



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STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

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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
6.7 MMI : Man Machine Interface
6.8 HMI : Human Machine Interface
6.9 SLS : Sodium Lauryl Sulphate

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: Cleaning and Operation of vacuum cleaner.

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure – I	Cleaning Checklist of Rapid Mixer Granulator with co-mill		Logbook

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 (03).

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	



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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I CLEANING CHECKLIST OF RMG WITH CO-MILL (Capacity 1200 Liters)

Name of the Equipment	RAPID MIXER GRANULATOR		
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No	Activity	Activity Performed
1.	Enter the cleaning start time equipment usage and cleaning log sheet as per SOP "Equipment usage and cleaning log book"	
2.	In "PNEUMATIC CONTROL" touch the purging air to OPEN and touch discharge valve to CLOSE and fill with purified water upto chopper height (approx.. 500 liters of purified water). Close the charging port.	
3.	Touch "MOTOR CONTROL" and start impeller and chopper in slow speed for 5 minutes to remove the adhesive material.	
4.	Place a suitable container beneath the discharge port of the RMG. Click on Bypass to bypass the bowl and then Open the discharge valve and drain the wash water.	
5.	Open all the clamps and remove the gaskets of charging port, vent filter, view glass and clean with 5-10 liters of purified water using nylon scrubber.	
6.	Clean the filter bag housing and hose pipe with 40-50 liters of purified water using nylon scrubber.	
7.	Open the lid of RMG and remove the the lid gasket and clean with 10-20 liters of purified water using nylon scrubber.	
8.	Remove the inverted cone shaped dome by turning the handles in anticlockwise direction.	
9.	Dismantle the impeller and chopper and clean with 30-50 liters of purified water using high pressure jet cleaner.	
10.	Turn off the mains.	
11.	Apply 80-140 liters of purified water to inner and outer surface using high pressure jet cleaner and scrub the machine intermittently with nylon scrubber/ Teflon scraper.	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Rapid Mixer Granulator with co-mill (Capacity 1200 Liters) make Kevin	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

12.	Clean the cleaned parts with 2% sodium Lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.	
13.	After scrubbing clean the parts with 50-120 liters of purified water using high pressure jet cleaner.	
14.	Clean the chopper motor cover, fixed lifter outer body, fixed lifter base, railing and co-mill motor cover with wet cloth dipped in purified water.	
15.	Clean the control panel, limit switch, the utility cables by using a dry lint free cloth.	
16.	Scrub the inside of the RMG with nylon scrubber using 70-80 liters of purified water.	
17.	Scrub the outside, lid and platform of RMG with a nylon scrubber using 40-50 liters of purified water.	
18.	Wash the discharge port and discharge valve with 50-60 liters of purified water using high pressure jet cleaner and scrub intermittently with nylon scrubber	
19.	Dis-mental the shroud and scrub the deposited material from inner side of shroud and co-mill screen if used with 20-30 liters of purified water.	
20.	Rinse the agitator, chopper, discharge valve, inside lid, outside, shroud and platform of the RMG with 90-120 liters of purified water.	
21.	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 purified water with nylon scrubber. Fit the panel covering and side covers back in place.	
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. Close the discharge valve and top lid.	
23.	Record the cleaning completion time in equipment usage log sheet as per SOP.	
24.	Ensure that area is cleaned as per SOP.	
25.	Replace the "UNDER CLEANING" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.	
26.	Before reassembling 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