



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Rapid Mixer Granulator 150 liter	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning of Rapid Mixer Granulator 150 litre. (Bectochem)

2.0 SCOPE:

This SOP is applicable to the cleaning of Rapid Mixer Granulator 150 litre (Bectochem) located in granulation.

3.0 RESPONSIBILITY:

Production : Technical Associate/Officer/Executive/Assistant Manager

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 TYPE A:

Change over from one batch to next batch of the same product and potency and of similar product with ascending potency.

4.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine with date and signature of the production officer.

4.1.2 Enter the cleaning start time in equipment sequential log book as per SOP.

4.1.3 Ensure that the main power supply is switched OFF.

4.1.4 Scrub the deposited material of the RMG from inside with the help of spatula.

4.1.5 Clean the inner and outer sides of the RMG and electrical panel with the help of dry lint free cloth.

4.1.6 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production officer.

4.1.7 Record the cleaning completion time in equipment sequential log book as per SOP.

4.2 TYPE B:



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This is a cleaning procedure for Change over of product with different actives/color/ descending potency or after maintenance of contact parts.

- 4.2.1 Replace the "TO BE CLEANED" status label with "UNDER CLEANING" status label with date and signature of the Production officer.
- 4.2.2 Enter the cleaning start time in equipment sequential log book as per SOP.
- 4.2.3 Cover the MMI, all electrical panel and motors with the help of polyethylene bags.
- 4.2.4 Select the 'WASH' mode on MMI and operate the touch screen of the RMG to close the discharge valve.
- 4.2.5 Open the lid and fill approx. 30.0 to 40.0 kg purified water.
- 4.2.6 Close the lid and run the RMG at slow speed for 5 minutes with the chopper ON.
- 4.2.7 Place a suitable container beneath the discharge port of the RMG.
- 4.2.8 Open the discharge valve and drain the wash water.
- 4.2.9 Switch "OFF" the mains.
- 4.2.10 Dismantle lid of charging port, gasket, clamps and RMG vent filter screw.
- 4.2.11 Apply approx. 5.0 to 10.0 kg of purified water and scrub the above parts with nylon scrubber.
- 4.2.12 Clean the RMG vent filter with approx. 5.0 to 10.0 kg of purified water and scrub with nylon scrubber.
- 4.2.13 After scrubbing with nylon scrubber clean all the parts with approx. 10.0 to 15.0 kg purified water.
- 4.2.14 Open the lid of the RMG and remove the inverted cone shaped dome by turning the handles in a clockwise direction.
- 4.2.15 Clean the cone shaped dome with approx. 10.0 to 15.0 kg purified water till the traces of previous product removed.
- 4.2.16 Lift the agitator with the help of touch screen and clean the lower and upper parts of agitator by nylon scrubber.
- 4.2.17 Wash the agitator same way with approx. 15.0 to 20.0 kg of purified water.
- 4.2.18 Dismantle the chopper by turning the bolt holding the blades in anti- clockwise direction.
- 4.2.19 Wash chopper with approx. 10.0 to 15.0 kg of purified water and scrub with nylon scrubber.



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- 4.2.20 Clean chopper blade with approx. 10.0 to 15.0 kg of purified water.
- 4.2.21 Scrub the inside of the RMG with nylon scrubber and wash it with approx. 20.0 to 30.0 kg of purified water.
- 4.2.22 Scrub the outer body, lid and platform of RMG with a nylon scrubber and wash using approx. 30.0 to 40.0 kg of purified water.
- 4.2.23 Scrub the discharge port by nylon scrubber. Wash it with approx. 15.0 to 20.0 kg of purified water.
- 4.2.24 Rinse the agitator, chopper, discharge valve, inside lid, discharge port, outside and platform of the RMG with approx. 40.0 to 60.0 kg of purified water.
- 4.2.25 Unscrew the motor covers from front and backside. Dry clean the machine from inside using dry lint free cloth and clean underneath of the RMG. Fit the panel cover and side covers back in place.
- 4.2.26 Dry the all parts with compressed air followed by clean dry lint free cloth.
- 4.2.27 Remove the polyethylene bags and clean the chopper motor cover and shaft, fixed lifter outer body, fixed lifter base, control panel, limit switch, railings and the utility cables by wiping with clean dry lint free cloth.
- 4.2.28 Reassemble the dome, chopper assembly and other parts in reverse order of dismantling.
- 4.2.29 Wipe out all parts of RMG with wet lint free cloth soaked in 70% IPA v/v. discharge valve.
- 4.2.30 Switched on the main and operate the touch screen to down the agitator and to close the discharge valve.
- 4.2.31 Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer.
- 4.2.32 Record the cleaning completion time in equipment sequential log book as per SOP.

Precaution: Ensure that agitator blade and chopper blade are not lies in same position.

5.0 ANNEXURE (S) :

Annexure I : Cleaning checklist of RMG 150 litre.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Procedure for area line clearance.

7.0 ABBREVIATION (S) /DEFINITION (S) :

FBD : Fluidized Bed Dryer

IPA : Isopropyl Alcohol

Q.A. : Quality Assurance

RMG : Rapid Mixer Granulator

SOP : Standard Operating Procedure

V/V : Volume / Volume

Kg : Kilogram

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---