STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**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 Rapid Mixer Granulator (BECTOCHEM, Capacity 600 Liters).

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation procedure of Rapid Mixer Granulator (BECTOCHEM, Capacity 600 Liters), in the production.

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 (WITH MODIFIED HMI):

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 "EQUIPMENT STATUS" label and affix dully-filled "TO BE CLEANED" label to the machine. Before start the cleaning affix "UNDER CLEANING" label.

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 Affix dully filled 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 and cleaning 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 "EQUIPMENT STATUS" label and affix dully filled "TO BE CLEANED" label to the machine**.** Before start the cleaning affix "UNDER CLEANING" label.

5.2.2 Enter the cleaning start time in equipment usage and cleaning 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 touch screen of the RMG to close the discharge port. Open the lid and fill 50 liters of purified. Close the top lid of RMG.

5.2.6 Turn washing mode ON by moving the Prod/ Wash button to clockwise direction. Touch the "WIP MODE" icon. On the main LOGIN screen.

5.2.7 Turn WASH MODE ON by Touching WASH MODE (ON/OFF) icon.

5.2.8 Fill the following parameters

- Product code
- Batch No.
- Operator code

And touch NEXT icon.

5.2.9 Following parameters will appear on the screen

WASH MODE ON		
• Chopper clearance OK		
	Set	Act
• Impeller Slow Speed	--- RPM	---
• Impeller Fast Speed	--- RPM	---
• Impeller Current --- A		
• Chopper Current --- A		
PREVIOUS	MAIN MENU	NEXT

5.2.10 Set the RPM of impeller at the slow speed(55 RPM).Touch on "NEXT" ICON.

WASH MODE ON		
IMPLLER SLOW ON/OFF	IMPLLER FAST ON/OFF	
CHOPPER SLOW ON/OFF	CHOPPER FAST ON/OFF	
DISCHARGE OPEN OFF	DISCHARGE CLOSE OFF	
MAIN	PREVIOUS	NEXT

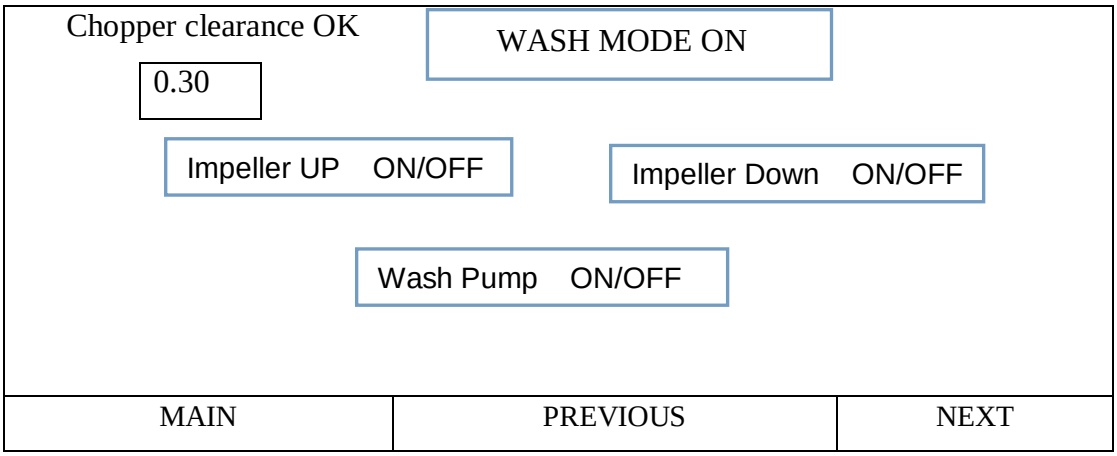
5.2.11 Run the impeller and chopper by touching Impeller slow ON/OFF and chopper slow ON/OFF icon and run the impeller for 5 minutes.

5.2.12 Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.

5.2.13 Put 'OFF' the mains.

5.2.14 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.

5.2.15 Touch on NEXT icon and these options will appear



5.2.17 Lift the impeller UP, by touching "IMPELLER UP" icon.

5.2.18 Clean the impeller and surface below impeller with the help of nylon scrubber and purified water.

5.2.19 Clean the RMG filter bag with 2-5 liter of purified water and dry it along with the FBD finger bags.

5.2.20 After scrubbing clean the parts with 10-12 liters of purified water.

5.2.21 Clean the RMG; chopper motor cover, fixed lifter outer body, fixed lifter base with wet cloth dipped in purified water.

5.2.22 Clean the control panel, limit switches, railings and the utility cables by using a dry lint free cloth.

5.2.23 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.

5.2.24 Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.

5.2.25 Clean the agitator blade and chopper blade 10-12 liters of purified water by scrubbing with nylon scrubber.

5.2.26 Clean the agitator blade and chopper blade with 15 to 20 liters of purified water

5.2.27 Scrub the inside of the RMG with nylon scrubber using 60 – 70 liters of purified water.

5.2.28 Scrub the outside, lid and platform of RMG with a nylon scrubber using purified water.

5.2.29 Unscrew the panel coving on the front side and outside covers. Dry clean the machine from inside using vacuum cleaner and dry lint free duster. Clean the underneath the machine. Cle the side covers by using purified water with nylon scrubber. Fit the panel covering and side covers back in place.

5.2.30 Wash the discharge port by scrubbing the area with a nylon scrubber using 10-15 liters of purified water.

5.2.31 Clean the RMG filter bag with purified water and dry it along with FBD finger bags as per SOP.

5.2.32 Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 30 – 45 liters of purified water.

5.2.33 Reassemble the agitator blades, dome and chopper assembly in reverse order of dismantling.

5.2.34 Ensure that area is cleaned as per SOP.

5.2.35 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.

5.2.36 Replace the "UNDER CLEANING" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.

5.2.37 Record the cleaning completion time in equipment usage log sheet as per SOP.

5.2.38 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. If the cleaned equipment has been idle for less than 72 hours no mopping is required before execution of batch. If the cleaned equipment has been idle for 72 hours or more but less than 240 hours/10 days after type –B cleaning, then re clean the equipment by mopping with 70 % v/v IPA solution prior to use. if the cleaned equipment has been idle for 240 hrs/10 days or more after type B cleaning, then re clean the equipment by following the type B cleaning prior to use.**

5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / colour / 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 is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry lint free cloth.

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

5.4.1.2 Ensure that the compressed air and main electric supply is 'ON' from service Area and Ensure discharge valve is closed.

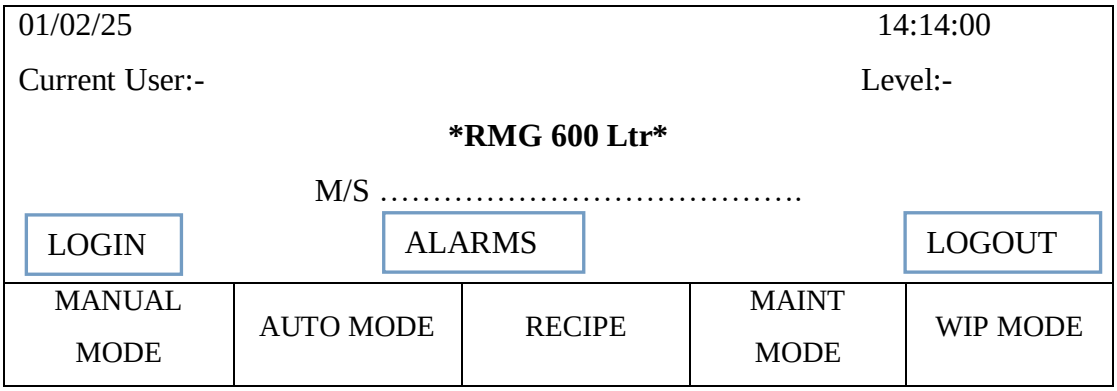
5.4.1.3 Turn Control 'ON/OFF' switch on control panel to 'ON' position. Opening screen will open on HMI.

5.4.1.4 Ensure that Compressed air pressure on pressure gauge is approximately 5 Bar if not, adjust by turning Lock knob in clockwise direction to increase the Pressure and anticlockwise to decrease the pressure.

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 Event procedure as per SOP.

5.4.1.6 Turn on the black selector switch to ON position on the control panel.

5.4.1.7 Home screen will appear as below-



5.4.1.8 Touch ON LOGIN icon on HMI for Login.

5.4.1.9 Login by entering operator name and password by touching the alphanumeric keys then touch ENTER for confirmation.

5.4.1.10 After confirmation of password from main screen operates the machine in manual mode, auto mode, recipe edit/ load, maintenance mode and wip mode as required.

5.4.2 Recipe Edit / Load

5.4.2.1 Touch the recipe icon on the HMI, recipe screen open.

5.4.2.2 Here add the Product name, Equipment ID, Batch No. , Lot No., User Name and Current Recipe.

5.4.2.3 Touch ‘RECIPE EDIT’ for editing the current recipe.

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.4.2.4 Set the following parameters for DRY MIXING as per respective BMR:

Recipe Name:---

DRY MIXING

IMPELLER TIME : _____MIN.

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____SLOW/ FAST

CHOPPER SELECTION :_____ ON / OFF

NO. OF STAGE :_____NO.

END POINT CURRENT -I :_____AMPERE

END POINT CURRENT -II :_____ AMPERE

5.4.2.5 Touch next icon for set the following parameters for wet mixing as per BMR:-

BINDER ADDITION 1

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

GRANULATION-1

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

BINDER ADDITION 2

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-2

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ADDITIONAL QUANTITY

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-3

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-4

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-5

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

GRANULATION-6

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-7

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-8

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

GRANULATION-9

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

GRANULATION-10

IMPELLER TIME :_____SEC

CHOPPER SLOW TIME :_____SEC

CHOPPER FAST TIME :_____SEC

IMPELLER SELECTION :_____ SLOW/FAST

CHOPPER SELECTION :_____ ON /OFF

IMPELLER & CHOPPEER SPEED

Impeller Slow Speed : 55 RPM

Impeller Slow Speed : 110 RPM

Chopper Slow Speed : 1440 RPM

Chopper Fast Speed : 2880 RPM

Note: 1) In each run the actual time on print shown either equal or1 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) Each chopper cycle 1 sec less then set time.

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

5) After completion of each cycle ACK icon touch for next cycle after completion of all set cycle DISCHARGE OVER icon touch for batch summary.

5.4.2.7 Before touch on SAVE RECIPE icon select RECORD NAME and touch SAVE RECIPE icon to save the edited recipe. Touch on AUOTMODE PARAMETER icon and touch on LOAD RECIPE icon. Select recipe from RECORD NAME and touch LOAD RECIPE.

5.5 Auto Mode Operation

5.5.1 Touch AUTO MODE icon on the HMI.

5.5.2 Turn Auto mode ON by touching on AUTO MODE ON/OFF icon.

5.5.3 These parameters will appear on HMI

AUTO CYCLE OVER AUTO MODE ON

Granulation cycle:- 0 Impeller current -------A

Chopper current -------A

Current cycle time:- ___sec

Auto cycle on:- ___min___sec

Auto cycle paused:- -----min-----sec

START	PAUSE	RESET	ACK	PRINT RECIPE	PRINT PREVIEW

MAIN ALARMS AUTO MODE OPERATION AUTO DISCHARGE

5.5.4 Before touch START icon touch the RESET icon first. Touch START icon to start a cycle of the recipe loaded or PAUSE icon to pause the cycle and ACK for next cycle (e.g. Binder addition, granulation 1,Binder addition 2, Granulation 2,addition Quantity, granulation 3, granulation 4, granulation 5,granulation 6,granultion 7,granultion 8, granulation 9 & granulation 10).

5.5.5 **For Discharge Cycle**

5.5.5.1 Touch AUTO DISCHARGE icon on HMI screen in auto mode .

5.5.5.2 The screen will shows as:

AUTO MODE

CHOPPER ON/OFF

SET ACTUAL

IMPELLER CREEP SPEED: ____RPM ----------

ACTUAL

IMPELLER CURRENT: _____A

CHOPPER CURRENT: _____A

AUTO MODE	DISCHARGE START	DISCHARGE STOP	DISCHARGE OVER	BACK

5.5.5.3 To start the discharge cycle touch 'DISCHARGE START', discharge done.

5.5.5.4 The impeller creep speed, and impeller and chopper current will show on HMI.

To stop discharge cycle touch on DISCHARGE STOP and than long touch on DISCHARGE OVER.

5.6 Manual Mode Operation

5.6.1 Touch MANUAL MODE icon for manual mode operation.

5.6.2 Turn on manual mode by touching MANUAL MODE ON/OFF icon.

5.6.3 Add product code, Batch No. and Operator Code.

5.6.5 For Dry Mixing

Touch MANUAL DRY for dry mixing screen appear :

5.6.5.1 Touch MANUAL DRY for dry mixing screen appear :

DRY MIXING CYCLE		
DRY MIXING ON/OFF ACT IMPELLER CURRENT:- ____A IMPELLER SPEED :- ____RPM CHOPPER CURRENT: ____A		
PREVIOUS	MAIN MENU	NEXT

Impeller current and chopper current will show when impeller and chopper are ON.

5.6.5.2 Touch DRY MIXING ON/OFF icon it change to ON touch NEXT icons will appear

DRY MIXING CYCLE		
IMPELLER SLOW ON/OFF		CHOPPER SLOW ON/OFF
IMPELLER FAST ON/OFF		CHOPPER FASTON/OFF
MAIN MENU	PREVIOUS	NEXT

From above icons impeller/chopper will be ON/OFF i.e. SLOW/FAST.

To see the impeller current / impeller speed / chopper current touch on PREVIOUS icon.

5.6.6 For Wet Mixing

5.6.6.1 Touch on MANUAL WET icon screen will appear:-

WET MIXING CYCLE		
WET MIXING CYCLE ON/OFF		
	ACT	
	IMPELLER CURRENT:- ____A	
	IMPELLER SPEED :- ____RPM	
	CHOPPER CURRENT: ____A	
PREVIOUS	MAIN MENU	NEXT

5.6.6.2 Touch WET MIXING CYCLE ON/OFF icon it change to ON , then touch NEXT icon option appears:-

WET MIXING CYCLE		
IMPELLER SLOW ON/OFF		CHOPPER SLOW ON/OFF
IMPELLER FAST ON/OFF		CHOPPER FASTON/OFF
MAIN MENU	PREVIOUS	NEXT

Impeller current and chopper current will show when impeller and chopper are ON. From above icons impeller/chopper will be ON/OFF i.e. SLOW/FAST.

5.6.6.3 Add the required quantity of binder solution in RMG as per Respective BMR. Run the impeller and chopper as per Respective BMR.

5.6.6.4 Continue mixing till the ampere load as specified in respective BMR is achieved.

5.6.7 For Discharge Cycle

5.6.7.1 Touch MANUAL DISCHARGE icon in manual mode screen will appear:-

DISCHARGE CYCLE		
DISCHARGE CYCLE ON/OFF		
	SET	ACT
IMPELLER CREEP SPEED:-	___RPM	___RPM
IMPELLER CURRENT :-		____A
CHOPPER CURRENT:-		____A
PREVIOUS	MAIN MENU	NEXT

Touch on DISCHARGE CYCLE ON/OFF icon it change to ON , touch NEXT icon option appear:-

DISCHARGE CYCLE		
IMPELLER CREEP ON/OFF		CHOPPER CREEP ON/OFF
DISCHARGE OPEN ON/OFF		DISCHARGE CLOSEON/OFF
MAIN	PREVIOUS	NEXT

From above icons impeller/chopper creep will be ON/OFF and discharge will be open and close.

5.6.7.5 **Note**: Ensure the purging air supply is compressed air or Nitrogen air as per requirement (If applicable).

5.7 PROCEDURE (WITHOUT MODIFIED HMI)

5.7.1 "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.

5.7.1.1 Remove "EQUIPMENT STATUS" label and affix dully-filled "TO BE CLEANED" label to the machine. Before start the cleaning affix "UNDER CLEANING" label.

5.7.1.2 Record the cleaning completion time in equipment usage and cleaning log sheet as per SOP.

5.7.2 "TYPE B" CLEANING

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

5.7.2.1 Remove "EQUIPMENT STATUS" label and affix dully filled "TO BE CLEANED" label to the machine**.** Before start the cleaning affix "UNDER CLEANING" label.

5.7.2.2 Enter the cleaning start time in equipment usage and cleaning log sheet as per SOP.

5.7.2.3 Open all the clamps, remove all the gaskets and clean with 5-10 liters of purified water.

5.7.2.4 Cover the control panel with poly bag to avoid water entry in to them.

5.7.2.5 Operate the touch screen of the RMG to close the discharge port. Open the lid and fill 50 liters of purified. Close the top lid of RMG.

5.7.2.6 Turn washing mode ON by moving the Prod/ Wash button to clockwise direction. Press WIP soft key on the main LOGIN screen.

5.7.2.7 Turn WASHING MODE ON by pressing ENTER soft key when cursor Blinks on ON/ OFF.

5.7.2.8 Fill the following parameters

- Product code
- Batch No.
- Operator Name

And Press NEXT soft key.

5.7.2.9 Following parameters will appear on the screen

- Impeller Slow Speed
- Impeller Fast Speed

5.7.2.10 Set the RPM of impeller at the slow speed.

5.7.2.11 Press Up and Down keys to move the curser, close the lid and run the impeller and chopper by moving the curser to ON and press ENTER soft key and run the impeller for 5 minutes.

5.7.2.12 Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.

5.7.2.13 Put 'OFF' the mains.

5.7.2.14 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.

5.7.2.15 Press ENTER and these options will appear

Impeller UP ON/OFF Impeller Down ON/OFF

Wash Pump ON/ OFF

5.7.2.16 Press Up and Down soft key to move the curser.

5.7.2.17 Lift the impeller UP, by pressing enter when curser blinks at the ON position.

5.7.2.18 Clean the impeller and surface below impeller with the help of nylon scrubber and purified water.

5.7.2.19 Clean the RMG filter bag with 2-5 liter of purified water and dry it along with the FBD finger bags.

5.7.2.20 After scrubbing clean the parts with 10-12 liters of purified water.

5.7.2.21 Clean the RMG; chopper motor cover, fixed lifter outer body, fixed lifter base with wet cloth dipped in purified water.

5.7.2.22 Clean the control panel, limit switches, railings and the utility cables by using a dry lint free cloth.

5.7.2.23 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.

5.7.2.24 Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.

5.7.2.25 Clean the agitator blade and chopper blade 10-12 liters of purified water by scrubbing with nylon scrubber.

5.7.2.26 Clean the agitator blade and chopper blade with 15 to 20 liters of purified water

5.7.2.27 Scrub the inside of the RMG with nylon scrubber using 60 – 70 liters of purified water.

5.7.2.28 Scrub the outside, lid and platform of RMG with a nylon scrubber using purified water.

5.7.2.29 Unscrew the panel coving on the front side and out side covers. Dry clean the machine from inside using vacuum cleaner and dry lint free duster. Clean the underneath the machine. Cle the side covers by using purified water with nylon scrubber. Fit the panel covering and side covers back in place.

5.7.2.30 Wash the discharge port by scrubbing the area with a nylon scrubber using 10-15 liters of purified water.

5.7.2.31 Clean the RMG filter bag with purified water and dry it along with FBD finger bags as per SOP.

5.7.2.32 Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 30 – 45 liters of purified water.

5.7.2.33 Reassemble the agitator blades, dome and chopper assembly in reverse order of dismantling.

5.7.2.34 Ensure that area is cleaned as per SOP.

5.7.2.35 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.

5.7.2.36 Replace the “TO BE CLEANED” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.

5.7.2.37 Record the cleaning completion time in equipment usage log sheet as per SOP.

5.7.2.38 Record the cleaning activity in Annexure I.

5.7.3 Frequency

5.7.3.1 **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. If the cleaned equipment has been idle for less than 72 hours no mopping is required before execution of batch. If the cleaned equipment has been idle for 72 hours or more but less than 240 hours/10 days after type –B cleaning, then re clean the equipment by mopping with 70 % v/v IPA solution prior to use. if the cleaned equipment has been idle for 240 hrs/10 days or more after type B cleaning, then re clean the equipment by following the type B cleaning prior to use.**

5.7.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / colour / 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.

5.7.3.3 Cleaning is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry lint free cloth.

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.

5.7.4 OPERATION

5.7.4.1 Machine Setting

5.7.4.1.1 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.

5.7.4.1.2 Ensure that the compressed air and main electric supply is 'ON' from service Area and Ensure discharge valve is closed.

5.7.4.1.3 Turn Control 'ON/OFF' switch on control panel to 'ON' position. Opening screen will open on MMI.

5.7.4.1.4 Ensure that Compressed air pressure on pressure gauge is approximately 5 Bar if not, adjust by turning Lock knob in clockwise direction to increase the Pressure and anticlockwise to decrease the pressure.

5.7.4.1.5 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.

5.7.4.1.6 Turn on the black selector switch to ON position on the control panel.

5.7.4.1.7 Home screen will appear as below-

03/04/25		***RMG 600 Ltr***			20:20:36	
M/S …….						
BECTOCHEM CONSULTANT & ENGINEERS PVT. LTD.						
F1: LOGIN						
MAIN	AUTO	RECIPE	MAINT	WIP		LOGOUT

5.7.4.1.8 Press F1 soft key on the MMI for Login.

5.7.4.1.9 Load correct password by pressing the alphanumeric keys then touch ENTER for confirmation.

5.7.4.1.10 After confirmation of password from main screen operates the machine in manual mode, auto made, recipe edit/ load, maintenance mode and wip mode as required.

5.7.4.2 Recipe Edit / Load

5.7.4.2.1 Press the recipe soft key on the MMI, recipe screen open.

5.7.4.2.2 Here add the Product Code, Batch No., and Operator Code.

5.7.4.2.3 Press ‘RECIPE EDIT’ for editing the current recipe.

5.7.4.2.4 Set the following parameters for DRY MIXING as per respective BMR:

Impeller Slow Time :_____min

Impeller Fast Time :_____min

Chopper on Delay Time :_____sec

Chopper Slow Time :_____min

Chopper Fast Time :_____min

Delay Time :_____min

Impeller Slow Speed :_____RPM

Impeller Fast Speed :_____RPM

5.7.4.2.5 Set the following parameters for Wet mixing as per BMR

Impeller Slow Time :_____min

Impeller Fast Time :_____min

Chopper on Delay Time :_____sec

Chopper Slow Time :_____min

Chopper Fast Time :_____min

Delay Time :_____min

Impeller Slow Speed :_____RPM

Impeller Fast Speed :_____RPM

5.7.4.2.6 Set the following parameters for Discharge Cycle as per BMR

Impeller Creep Speed

5.7.4.2.7 Press SAVE soft key to save the edited recipe and given it a suitable name.

5.7.5 Auto Mode Operation

5.7.5.1 Press AUTO soft key on the MMI.

5.7.5.2 Turn Auto mode ON by pressing right key and ENTER soft key and F1 to exit.

5.7.5.3 These parameters will appear on MMI

- Auto cycle on ___min___sec
- Auto cycle Paused ___min___sec

START	PAUSE	RESET	REPEAT YES	REPEAT ON	DISCHARGE CYCLE

5.7.5.4 Press START soft key to start a cycle of the recipe loaded or PAUSE soft key to pause the cycle.

5.7.5.5 Press RESET soft key to restart the cycle and repeat of cycle press.

'REPEAT YES' or 'REPEAT NO' soft key.

5.7.5.6 Press NEXT soft key to see the Ampere load of chopper and impeller.

AUTO MODE ON		
AUTO CYCLE OVER CURRENT RECIPE NAME: XYZ IMPELLER CURRENT : 0.0 A CHOPPER CURRENT : 0.0 A		
PREV		NEXT

And other parameters in next screen.

5.7.5.7 **For Discharge Cycle**

5.7.5.7.1 Press DISCHARGE CYCLE soft key on MMI.

5.7.5.7.2 The screen will shows as:

AUTO MODE					
AUTO CYCLE OVER AUTO CYCLE ON : 0 MIN 0 SEC AUTO CYCLE PAUSED : 0 MIN 0 SEC					
DISCHR START	DISCHR STOP	DISCHR OVER	REPEAT YES	REPEAT ON	NEXT

5.7.5.7.3 To start the discharge cycle press soft key ‘DISCHR START’, discharge done as per data entered in the recipe.

5.7.5.7.4 To see the impeller creep, chopper, impeller creep speed, and impeller and chopper current press soft key ‘NEXT’ on the MMI.

5.7.6 Manual Mode Operation

5.7.6.1 Press home soft key on MMI.

5.7.6.2 Press MAN soft key for manual mode operation.

5.7.6.3 Turn on manual mode by pressing ENTER soft key.

5.7.6.4 Add product code, Batch No. and Operator Code. These options will appear-

- Dry mixing
- Wet mixing
- Discharge Cycle

5.7.6.5 For Dry Mixing

5.7.6.5.1 Press Dry Mixing soft key on MMI and turn ON dry mixing Cycle by Pressing ENTER soft key and set the impeller speed as per requirement.

Dry Mixing Cycle ON

SET ACTUAL CURRENT

- Impeller slow speed :_____RPM
- Impeller Fast Speed :_____RPM
- Impeller Current : 0.0 A
- Chopper Current : 0.0 A

Impeller current and chopper current will show when impeller and chopper are ON.

5.7.6.5.2 Press NEXT soft key and following option will appear

- Impeller Slow ON/ OFF Impeller Fast ON/ OFF
- Chopper Slow ON/ OFF Chopper Fast ON/ FAST

Press Up and Down keys and when curser blinks on ON/ OFF, press Enter soft key to ON or press ENTER soft key to OFF.

5.7.6.6 For Wet Mixing

5.7.6.6.1 Press Wet mixing soft key on MMI.

5.7.6.6.2 Press Wet Mixing and turn ON Wet mixing cycle by Pressing ENTER soft key and set the following parameters

- Impeller slow Speed
- Impeller Fast Speed
- Impeller Current ___A
- Chopper Current ___A

Impeller current and chopper current will show when impeller and chopper are ON.

5.7.6.6.3 Add the required quantity of binder solution in RMG as per Respective BMR.

Press NEXT soft key and following option will appear

- Impeller Slow ON/ OFF Impeller Fast ON/ OFF
- Chopper Slow ON/ OFF Chopper Fast ON/ FAST

Press Up and Down keys and when curser blinks on ON/ OFF, press enter soft key to ON or OFF.

5.7.6.6.4 Continue mixing till the ampere load as specified in respective BMR is achived.

5.7.6.7 For Discharge Cycle

5.7.6.7.1 Press the Discharge Cycle soft key on MMI as mentioned in Point 5.6.4.

5.7.6.7.2 Set the following parameters for discharge of material from RMG

- Impeller Creep Speed :____RPM
- Impeller Current : 0.0 A
- Chopper Current : 0.0 A

5.7.6.7.3 Then press NEXT soft key and following parameters will appear

- Impeller Slow ON/ OFF Impeller Fast ON/ OFF
- Chopper Slow ON/ OFF Chopper Fast ON/ FAST

5.7.6.7.4 Press Up and Down key and when curser blinks on ON/ OFF, press Enter to ON/ or OFF.

5.7.6.7.5 **Note**: Ensure the purging air supply is compressed air or Nitrogen air as per requirement (If applicable).

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: Equipment Status Labeling

7.4 SOP: Cleaning and Utilization of FBD Finger Bag/ RMG Filter Bag

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Cleaning Checklist of Rapid Mixer Granulator (BECTOCHEM, Capacity 600 Liters)		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 (2)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details Of Revision	Effective Date
1.0	00		NEW SOP	NA	

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Rapid Mixer Granulator (Bectochem, Capacity 600 Liters)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I

CLEANING CHECKLIST OF RMG (BECTOCHEM, Capacity 600 Liters)

Name of the Equipment		**RAPID MIXER GRANULATOR**	
Equipment I.D. 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 50 liters of purified water.	
2	Remove all the gaskets and clean with 5-10 liters of purified water.	
3	Turn washing mode ON by moving the Prod/ Wash button to clockwise direction. Press WIP soft key on the main LOGIN screen.	
4	Turn WASHING MODE ON by pressing ENTER soft key when cursor Blinks on ON/ OFF.	
5	Fill the following parameters, Product code, Batch No., Operator Name and Press NEXT soft key.	
6	Following parameters will appear on the screen Impeller Slow Speed and Impeller Fast Speed.	
7	Set the RPM of impeller at the slow speed.	
8	Press Up and Down keys to move the curser, close the lid and run the impeller and chopper by moving the curser to ON and press ENTER soft key and run the impeller for 5 minutes.	
9	Place a suitable container beneath the discharge port of the RMG. Open the discharge valve and drain the wash water.	
10	Put 'OFF' the mains.	
11	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.	
12	Lift the impeller UP, by pressing enter when curser blinks at the ON position.	
13	Clean the impeller and surface below impeller with the help of nylon scrubber and purified water.	
14	Clean the RMG filter bag with 2-5 liter of purified water and dry it along with the FBD finger bags.	
15	Clean the cleaned parts with 2% sodium lauryl sulfate (for 1 liter 2% Sodium lauryl sulphate ,take 20 g sodium lauryl sulfate and dissolve in 1liter of purified water) if	

STANDARD OPERATING PROCEDURE

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

S.No.	Activity	Activity Performed
	previous product API is Efavirenz.	
16	After scrubbing clean the parts with 10-12 liters of purified water.	
17	Clean the RMG, chopper motor cover, fixed lifter outer body, fixed lifter base with wet cloth dipped in purified water.	
18	Clean the control panel, limit switches, railings and the utility cables by using a dry lint free cloth.	
19	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.	
20	Dismantle the chopper by turning the bolt holding the blades in an anticlockwise direction.	
21	Clean the agitator blade and chopper blade 10-12 liters of purified water by scrubbing with nylon scrubber.	
22	Clean the agitator blade and chopper blade with 15 to 20 liters of purified water	
23	Scrub the inside of the RMG with nylon scrubber using 60 – 70 liters of purified water.	
24	Scrub the outside, lid and platform of RMG with a nylon scrubber using purified water.	
25	Unscrew the panel coving on the front side and out side covers. Dry clean the machine from inside using vacuum cleaner and dry lint free duster. Clean the underneath the machine. Cle the side covers by using purified water with nylon scrubber. Fit the panel covering and side covers back in place.	
26	Wash the discharge port by scrubbing the area with a nylon scrubber using 10-15 liters of purified water.	
27	Clean the RMG filter bag with purified water and dry it along with FBD finger bags as per SOP.	
28	Rinse the agitator, chopper, discharge valve, inside lid, outside and platform of the RMG with 30 – 45 liters of purified water.	
29	Reassemble the agitator blades, dome and chopper assembly in reverse order of dismantling.	
30	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.