



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for operation of Rapid Mixer Granulator 150 litre.	Effective Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This procedure is applicable to the operation of Rapid Mixer Granulator 150 litre (Bectochem) located in granulation area.

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 Operation of RMG:

- 4.1.1 Ensure that the equipment is cleaned and ready for use.
 - 4.1.2 Replace the "CLEANED" status label with "UNDER PROCESS" status label with date and signature of the Production Officer.
 - 4.1.3 Switch "ON" the PLC.
 - 4.1.4 Ensure that the vent filter of RMG is properly fitted.
 - 4.1.5 Ensure that the discharge valve of RMG is closed.
 - 4.1.6 Turn the Black Key of control panel to "PRODUCTION" position.
 - 4.1.7 Operate the LPD for RMG as per SOP and bring the arm positioning the IPC with charging port of RMG.
 - 4.1.8 Ensure that the discharge valve of IPC aligns with the charging port of RMG.
 - 4.1.9 Open the butterfly valve of IPC to charge the material into the RMG.
 - 4.1.10 Ensure that no material shall remain in the IPC.
 - 4.1.11 Close the butterfly valve of IPC and bring it down by operating the LPD.
 - 4.1.12 Close the lid of the RMG and clamp it firmly with the help of toggle clamps.
 - 4.1.13 Place a cleaned FBD container bowl beneath the discharge chute of the RMG.
 - 4.1.14 Ensure that the emergency switch is released before operation.
- 4.2 To Run in "Manual Mode":**
- 4.2.1 Press LOGIN and screen will ask for password.
 - 4.2.2 Enter the password for level '2' and then press enter key.
 - 4.2.3 Select the MANUAL mode on the PLC and the screen will show the following parameters.

MANUAL BATCH PARAMETERS			
PRODUCT CODE :			
BATCH NO :			
OPERATOR CODE :			
MAIN	DRY	WET	DISCH
	MIXING	MIXING	



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4.2.4 On the above screen feed required parameter as per BMR and touch on 'DRY MIXING' key and the display will show following:

MANUAL MODE ON/OFF			
DRY MIXING CYCLE ON/OFF			
	SET	ACT	
IMPELLER SLOW ON/OFF	:	RPM	AMP
IMPELLER FAST ON/OFF	:	RPM	
CHOPPER SLOW ON/OFF	:	RPM	AMP
CHOPPER FAST ON/OFF	:	RPM	
PREV	MIMIC	EXIT	

4.2.5 On this screen we can operate impeller and chopper at slow or fast speed as per BMR. Press 'EXIT' key and go to manual batch parameter screen.

4.2.6 After completion of dry mixing cycle add binder as per instructions given in BMR.

4.2.7 Touch on 'WET MIXING' key and the screen will display the following:

MANUAL MODE ON/OFF			
WET MIXING CYCLE ON/OFF			
	SET	ACT	IMPELLER
SLOW ON/OFF	:	RPM	AMP
IMPELLER FAST ON/OFF	:	RPM	
CHOPPER SLOW ON/OFF	:	RPM	AMP
CHOPPER FAST ON/OFF	:	RPM	
PREV	MIMIC	EXIT	

4.2.8 On this screen we can operate Impeller and chopper at slow or fast speed as per BMR. Press 'EXIT' key and go to manual batch parameter screen.

4.2.9 Press 'DISCH' on manual mode screen for discharge cycle, display will show following.

MANUAL MODE ON/OFF			
DISCHARGE CYCLE ON/OFF			
	SET	ACT	
IMPELLER CREEP ON/OFF	:	RPM	AMP
CHOPPER CREEP ON/OFF	:	RPM	AMP
IMPELLER CONTINUOUS/INCH SELECTED			
PREV	MIMIC	NEXT	

4.2.10 On this screen feed required detail for operating the Impeller and chopper at creep speed. Press 'NEXT' key, display will show following screen:

MANUAL MODE ON/OFF			
* DISCHARGE CYCLE ON/OFF*			
DISCHARGE OPEN	SOV ON/OFF		
DISCHARGE CLOSE	SOV ON/OFF		
PREV	MIMIC	NEXT	



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4.2.11 After completion of wet mixing cycle discharge the material by operating the impeller and chopper on this screen. Operate the DISCHARGE ON/OFF to open and close the discharge valve.

4.3 To create the Recipe:

4.3.1 Press 'LOGIN' key on MMI and screen will ask for password.

4.3.2 Enter the password for level '3' and then press 'RECIPE' key and the screen will show the following.

AUTO BATCH PARAMETERS		
PRODUCT NAME :		
BATCH NO. :		
OPERATOR CODE :		
MAIN	RECIPE	RECIPE
	EDIT	LOAD

4.3.3 Touch on the 'RECIPE EDIT' key.

4.3.4 Enter the all parameters in recipe as per BMR and touch on 'NEXT' key after each stage and the screen shows as follows:

RECIPE EDIT - 1	
CURRENT RECIPE NAME :	
DRY MIXING PROCESS	
1. IMPELLER SLOW TIME	: ___ MIN
2. IMPELLER FAST TIME	: ___ MIN
3. CHOPPER ON DELAY TIME	: ___ SEC
4. CHOPPER SLOW TIME	: ___ MIN
5. CHOPPER FAST TIME	: ___ MIN
PREV	NEXT

RECIPE EDIT - 2	
CURRENT RECIPE NAME :	
6. IMPELLER SLOW SPEED	: ___ RPM
7. IMPELLER FAST SPEED	: ___ RPM
8. CHOPPER SLOW SPEED	: ___ RPM
9. CHOPPER FAST SPEED	: ___ RPM
10. DELAY TIME	: ___ RPM
PREV	NEXT



PHARMA DEVILS

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RECIPE EDIT - 3

CURRENT RECIPE NAME :

WET MIXING PROCESS

- 11. IMPELLER SLOW TIME : ___ MIN
- 12. IMPELLER FAST TIME : ___ MIN
- 13. CHOPPER ON DELAY TIME : ___ SEC
- 14. CHOPPER SLOW TIME : ___ MIN
- 15. CHOPPER FAST TIME : ___ MIN

PREV

NEXT

RECIPE EDIT - 4

CURRENT RECIPE NAME :

- 16. IMPELLER SLOW SPEED : ___ RPM
- 17. IMPELLER FAST SPEED : ___ RPM
- 18. CHOPPER SLOW SPEED : ___ RPM
- 19. CHOPPER FAST SPEED : ___ RPM

PREV

NEXT

RECIPE EDIT - 5

PRINT INTERVAL MIN
DISCHARGE CYCLE

- 20. IMPELLER CREEP SPEED : ___ RPM
- 21. CHOPPER CREEP SPEED : ___ RPM

IMPELLER INCH/CONTINUOUS SELECTED
PREV

NEXT

4.3.5 After entering of all parameters touch on 'NEXT' key and the screen will display all the added data as following:



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RECIPE EDIT - 6			
DRY MIXING PROCESS		WET MIXING PROCESS	
IMPELLER SLOW TIME	MIN	IMPELLER SLOW TIME	MIN
IMPELLER FAST TIME	MIN	IMPELLER FAST TIME	MIN
CHOPPER ON DELAY TIME	SEC	CHOPPER ON DELAY TIME	SEC
CHOPPER SLOW TIME	MIN	CHOPPER SLOW TIME	MIN
CHOPPER FAST TIME	MIN	CHOPPER FAST TIME	MIN
IMPELLER SLOW SPEED	RPM	IMPELLER SLOW SPEED	RPM
IMPELLER FAST SPEED	RPM	IMPELLER FAST SPEED	RPM
CHOPPER SLOW SPEED	RPM	CHOPPER SLOW SPEED	RPM
CHOPPER SLOW SPEED	RPM	CHOPPER FAST SPEED	RPM
DELAY TIME	MIN	PRINT INTERVAL	MIN
DISCHARGE CYCLE			
IMPELLER CREEP SPEED	RPM	IMPELLER CONTINUOUS/INCH SELECTED	
CHOPPER CREEP SPEED	RPM		
PREV	SAVE	DELETE	CHANGE PASSWORD
			EXIT

4.3.6 Touch on the 'SAVE' key and the screen will show the following:

SAVE RECIPE
REPLACE EXISTING
SAVE AS NEW
CANCEL

4.3.7 Select "SAVE AS NEW" option and enter the recipe name from alphanumerical screen and then press the 'ENTER' key and the screen will display as 'SAVING'.

4.3.8 Press the 'EXIT' key for exit.

4.3.1 To load the Recipe

4.3.1.1 Press 'LOGIN'.

4.3.1.2 Screen will ask for password

4.3.1.3 Enter the password for level '2'.

4.3.1.4 Press the 'RECIPE' key and the press 'RECIPE LOAD' key followed by select 'LOAD' key and the screen will show list of recipe.

4.3.1.5 Select the required recipe and the screen will display:

WARNING
LOAD RECIPE.....
YES NO

4.3.1.6 Press 'YES' Key to load recipe.

4.3.1.7 Press 'EXIT' key on PLC.

4.3.1.8 After loading of recipe go to Auto mode and run the RMG in auto mode.

4.4 To Run in "Auto Mode":

4.4.1 To run the selected recipe:

4.4.1.1 Press 'LOGIN' and screen will ask for password.

4.4.1.2 Enter the password for level '2'

4.4.1.4 Then run the RMG in auto mode by pressing 'AUTO' key on PLC.



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AUTO MODE ON/OFF

AUTO CYCLE OVER

CURRENT RECIPE NAME :
AUTO CYCLE ON : MIN SEC
AUTO CYCLE PAUSED : MIN SEC

ACT

IMPELLER CURRENT : AMP
CHOPPER CURRENT : AMP
REPEAT YES REPEAT NO DISCHARGE

MAIN START STOP RESET NEXT

4.4.1.5 Press 'START' key to start the RMG in auto mode.

4.4.1.6 Press 'NEXT' key, to show the process parameters, display will show following screen:

AUTO MODE ON/OFF

AUTO CYCLE OVER

SET ACT

DRY IMP. SLOW TIME MIN MIN
DRY IMP. FAST TIME MIN MIN
DRY CHOP. DELAY TIME SEC SEC
DRY CHOP. SLOW TIME MIN MIN
DRY CHOP. FAST TIME MIN MIN
DRY IMP. SLOW SPEED RPM
DRY IMP. FAST SPEED RPM AMP
DRY CHOP. SLOW SPEED RPM
DRY CHOP. FAST SPEED RPM AMP
DELAY TIME MIN MIN

PREV MIMIC NEXT



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4.4.1.7 Press 'NEXT' key, display will show following screen:

AUTO MODE ON/OFF		
AUTO CYCLE OVER		
	SET	ACT
WET IMP. SLOW TIME	MIN	MIN
WET IMP. FAST TIME	MIN	MIN
WET CHOP. DELAY TIME	SEC	SEC
WET CHOP. SLOW TIME	MIN	MIN
WET CHOP. FAST TIME	MIN	MIN
WET IMP. SLOW SPEED	RPM	
WET IMP. FAST SPEED	RPM	AMP
WET CHOP. SLOW SPEED	RPM	
WET CHOP. FAST SPEED	RPM	AMP
PREV	MIMIC	NEXT

4.4.1.8 Press the 'PREV' key two times and then press the 'DISCHARGE' key, display will show following screen:

AUTO MODE ON/OFF		
AUTO CYCLE OVER		
	SET	ACT
IMPELLER CREEP SPEED	RPM	AMP
CHOPPER CREEP SPEED	RPM	AMP
COMILL SPEED	RPM	RPM
IMPELLER INCH/CONTINUOUS SELECTED		
IMPELLER CREEP ON/OFF		
CHOPPER CREEP ON/OFF		
PREV	DISCH START	DISCH STOP
		DISCH OVER
		MAIN

4.4.1.9 On this screen actual RPM and current for impeller and chopper will display and after completion of wet mixing discharge the wet mass by operating the 'DISCH START' and 'DISCH STOP' key.

4.5 Record the operation time in equipment sequential log book as per SOP.

4.6 Replace the 'UNDER PROCESS' status label with 'TO BE CLEANED' status label with date and signature of the Production Officer.

4.7 Switch "OFF" the main.



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5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

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

SOP: Procedure for area line clearance.

SOP: Operation of Lifting and Positioning Device (SAAN)

7.0 ABBREVIATION (S))/DEFINITION (S):

BMR : Batch Manufacturing Record

IPC : In-Process Container

PLC : Programmable Logic Control

RMG : Rapid Mixer Granulator

SOP : Standard Operating Procedure

FBD : Fluidized Bed Dryer

QA : Quality Assurance

LPD : Lifting and Positioning Device.



PHARMA DEVILS

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REVISION CARD

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