



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Fluidized Bed Dryer (Bectochem)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Fluid Bed Dryer (BECTOCHEM).

### 2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Fluid Bed Dryer (BECTOCHEM) located in manufacturing 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 "EQUIPMENT STATUS" label and affix dully-filled "UNDER CLEANING" label to the machine.
- 5.1.2 Enter the cleaning start time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.1.3 Shake the finger bag in manually mode to dedust.
- 5.1.4 Remove the remaining of the previous batch from the equipment and the area with vacuum cleaner as per SOP (Cleaning and operation of vacuum cleaner).
- 5.1.5 Allow sucking the powder attached with the wall and return raiser using vacuum cleaner.
- 5.1.6 Clean the plenum, bag chamber, inlet and outlet air ducts from outside using a dry clean lint free duster.
- 5.1.7 Clean the product container bowl with dry lint free cloth to remove any left-over material.



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- 5.1.8 Affix dully filled status label on FBD as “CLEANED” 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 (Making entries in equipment usage and cleaning log sheet).
- 5.2 **“TYPE B” CLEANING:**  
This is a cleaning procedure for Changeover of product with different actives / colour / descending potency or after maintenance of contact parts.
- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.4.
- 5.2.2 Bring down the finger bag by operating the finger bag holding ring towards lower side.
- 5.2.3 Remove the bag from the finger holding ring and clean the bag and clean the bag as per SOP (Cleaning And Utilization of FBD Finger Bag / RMG Filter Bag).
- 5.2.4 Pull out the product container bowl; dismantle the view glass (1 nos.) of product container bowl and viewing glass (2 nos.) of bag chamber.
- 5.2.5 Scrub the bag chamber, explosion chamber and finger bag holder ring and view glasses with gasket, inflated gasket (2 nos.), inflated tube ring with a nylon scrubber using purified water from inside and outside to remove any adhered material.
- 5.2.6 Cleaning shall be performed for the Inlet Duct and Outlet Duct prior to dampers with high pressure jet cleaner and cleanliness shall be ensured up to maximum accessible area.
- 5.2.7 Use the ladder to clean the outer surface bag chamber.
- 5.2.8 Rinse all the above parts with 130-150 liters of purified water.
- 5.2.9 Scrub the product container bowl and trolley with a nylon scrubber using purified water.
- 5.2.10 Remove the gasket Dutch weave sieve and the supporting plate.
- 5.2.11 Place the sieve in a horizontal position. Scrub the sieve with a nylon scrubber using 30-40 liters of purified water.
- 5.2.12 Scrub the supporting plate with a nylon scrubber using purified water.
- 5.2.13 Rinse the product container bowl, sieve and supporting plate with 40-50 liters of Purified water.
- 5.2.14 Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate.
- 5.2.15 Scrub the outside of the FBD, supporting arms inlet air duct and the inlet chamber with a nylon scrubber using 40-50 liters of purified water.



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- 5.2.16 Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.
- 5.2.17 Clean the utility cables limit switches and control panel with a dry lint free duster.
- 5.2.18 Reassemble the view glasses of product container of bowl and bag chamber.
- 5.2.19 Put the cleaned FBD finger bag and RMG filter bag in FBD bowl.
- 5.2.20 Assemble the FBD and operate the FBD at an inlet temperature of 65°C until the out let temperature is achieved 63 °C to 65 °C. Ensure the bags are completely dried Remove the bags and transfer it to the granulation spare area.
- 5.2.21 Rinse the FBD bowl, bag chamber, explosion chamber and view glasses with 40-50 liters of purified water.
- 5.2.22 Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.
- 5.2.23 Wipe all the above parts with 70% v/v IPA solution.
- 5.2.24 Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.25 Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.2.26 Record the cleaning activity in Annexure II (Cleaning checklist of FBD).

### 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 seven days then follow the procedure of type – B cleaning as per SOP (Cleaning Verification).
- 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 as per SOP (Cleaning Verification).
- 5.3.3 Cleaning is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry by 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 (Making entries in equipment usage and cleaning log sheet).



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### 5.4 OPERATION (With HMI modification):

#### 5.4.1 Machine setting:

5.4.1.1 Ensure 'CLEANED' label duly filled and signed is affixed on the equipment. Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet). Affix 'EQUIPMENT STATUS' label duly filled and signed on the equipment.

5.4.1.2 Turn main switch of PLC on 'ON' position.

5.4.1.3 Ensure the Compressed air pressure should be between 5.0 to 6.0 bars. Turn on the black selector switch to 'ON' position on the control panel.

5.4.1.4 Home Screen will appears as

Log in the system with password

There is 03 level password protection

Operator: To start stop the machine.

Supervisor: To start, stop the machine and to machine running parameters.

Administrator (Manager/Shift in charge): To start, stop the machine and to edit the machine running parameters, except configuration and calibration parameter

5.4.1.5 Press LOGIN and enter password with the help of keypad on the HMI.

5.4.1.6 Touch 'MAIN MENU' on HMI. Main menu screen will appear. Touch 'LOGIN' ON HMI. Keypad will appear. Load correct password by pressing the alphanumeric keys then touch 'ENTER' for confirmation.

5.4.1.7 Touch 'MANUAL' on HMI. Manual mode main screen will appear.

5.4.1.8 Touch 'BAG UP/DOWN' on HMI. Pneumatic cylinder will come down.

5.4.1.9 Fix the FBT supporting ring at the fringes of finger bag and tight the rope.

5.4.1.10 Fix each finger one by one on the respective hook on the finger bag hanger.

5.4.1.11 Clamp the finger bag hanger on the pneumatic cylinder.

5.4.1.12 Attach the compressed air supply pipes to FBT supporting ring. Then tight the FBT ring to FBD bag with help of FBD bag rope. Touch "BAG UP" on HMI. When bag on position then touch bag seal on HMI.

5.4.1.13 Air Pressure of pressure gauge shall be maintained between 2.0 – 2.5 Kg/cm<sup>2</sup>. FBD by default stopped during process, if FBT pressure is not with in limit (2.0 – 2.5 Kg/cm<sup>2</sup>).

Note: Don't intervene the set value of FBT air pressure in between operation.



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5.4.1.14 Touch 'BAG UP' on HMI. Pneumatic cylinder will start lifting up. Manually guide the guide rollers into the track.

5.4.1.15 Touch Bowl to Chamber SEAL SOV on HMI. Pressure reading on the FBT pressure gauge shall increase to 2.0 to 2.5 bars.

5.4.1.16 Touch Upper and Lower SEAL' on HMI. Pressure reading on the PC pressure gauge shall increase to 2.0 to 2.5 bars.

**Note:** Turn OFF the main compressed air while hanging the FBD finger bag or Whenever the pneumatic cylinder is lifted lower.

### 5.4.2 **Recipe Edit / Load / Delete:**

5.4.2.1 Recipe can edited / loaded / deleted in both auto and manual mode.

5.4.2.2 Press RECIPE and set the following parameters

- Equipment ID : \_\_\_\_\_
- Product Name : \_\_\_\_\_
- Product Code : \_\_\_\_\_
- Batch No. : \_\_\_\_\_
- Lot No. : \_\_\_\_\_
- User Name : \_\_\_\_\_



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5.4.2.3 Press Recipe edit and following parameters will appear on HMI.

- Air Dry Time : \_\_\_\_\_min
- Drying Time 1 : \_\_\_\_\_min
- Drying Time 2 : \_\_\_\_\_min
- Drying Time 3 : \_\_\_\_\_min
- Drying Time 4 : \_\_\_\_\_min
- Drying Time 5 : \_\_\_\_\_min
- Drying Time 6 : \_\_\_\_\_min
- Drying Time 7 : \_\_\_\_\_min
- Piston Off Time : \_\_\_\_\_sec
- Piston On Time : \_\_\_\_\_sec
- Cooling Time : \_\_\_\_\_min
- Shaking Interval : \_\_\_\_\_min
- Shaking duration : \_\_\_\_\_sec
- Piston down Time : \_\_\_\_\_sec
- Piston up Time : \_\_\_\_\_sec
- End Shaking Time : \_\_\_\_\_sec
- Exhaust Blower speed : \_\_\_\_\_RPM
- Steam Condensation On Time : \_\_\_\_\_sec
- Print Interval : \_\_\_\_\_min



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RECIPE	
AIR DRY TIME :	2 MIN
DRYING TIME 1 :	2 MIN
DRYING TIME 2 :	2 MIN
DRYING TIME 3 :	2 MIN
DRYING TIME 4 :	2 MIN
DRYING TIME 5 :	2 MIN
DRYING TIME 6 :	2 MIN
DRYING TIME 7 :	2 MIN
PISTON OFF TIME :	1.8 SEC
PISTON ON TIME :	2.0 SEC
COOLING TIME :	2 MIN
SHAKING INTERVAL :	10 MIN
SHAKING DURATION :	30 SEC
PISTON DOWN TIME :	0.0 SEC
PISTON UP TIME :	1.8 SEC
END SHAKING TIME :	30 SEC
EX. BLOWER SPEED :	2000 RPM
STEAM COND. TIME :	40.0 SEC
PRINT INTERVAL :	1 MIN

5.4.2.4

SET

ALARM BAND

- Inlet Temperature : \_\_\_\_°C      \_\_\_\_°C
- Inlet Temperature high : \_\_\_\_°C
- Exhaust Temperature : \_\_\_\_°C



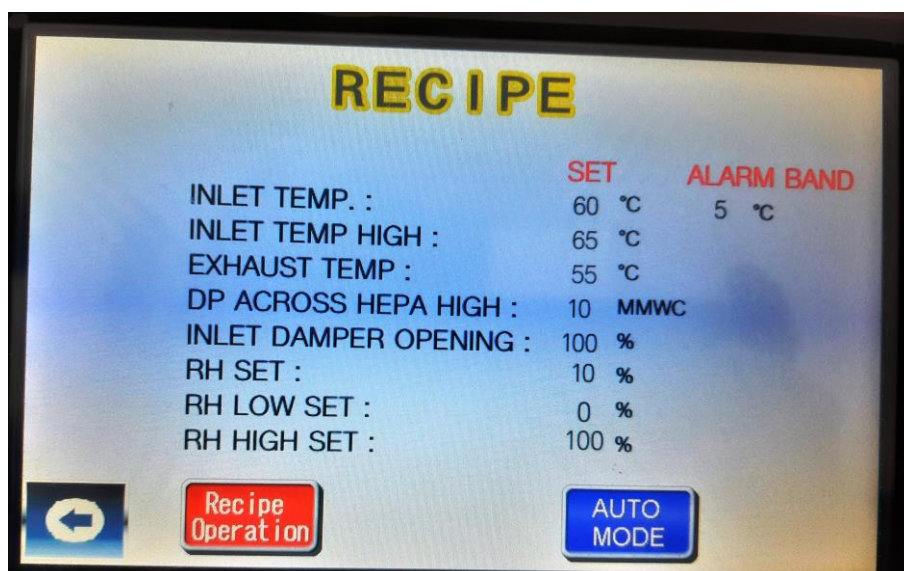
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- DP Across HEPA High : \_\_\_\_\_MM WC
- Inlet Damper Opening : \_\_\_\_\_%
- RH Set : \_\_\_\_\_%
- RH low : \_\_\_\_\_%
- RH High : \_\_\_\_\_%



- 5.4.2.5 Set the required parameters as specified in respective BMR.
- 5.4.2.6 Then press recipe operation to save a recipe (Save as new for new recipe if changes in parameter replace existing then press enter.
- 5.4.2.7 Load Product Name, Batch No., Equipment ID, Lot No., and User Name as per respective BMR.
- 5.4.2.8 Load Air Drying time, drying Time as per respective BMR.
- 5.4.2.09 Touch 'Recipe edit' on HMI. Keypad will open. Give suitable name or code for the recipe. Recipe will be get loaded in the PLC memory under given name or code.
- 5.4.2.10 To load already exist recipe Touch 'LOAD' on HMI. Stored recipe list will open. Select the recipe and touch 'load on HMI.
- 5.4.2.11 To delete already exist recipe touch 'Delete Recipe' on HMI. Stored recipe list will open. Select the recipe and touch 'Delete Recipe' on HMI. Warning 'Delete RECIPE XYZ' (XYZ indicates name or code for a particular recipe). Touch 'YES' to delete the selected recipe.
- 5.5 **Manual Mode Operation:**
- 5.5.1 Press 'LOGIN' and enter the password.





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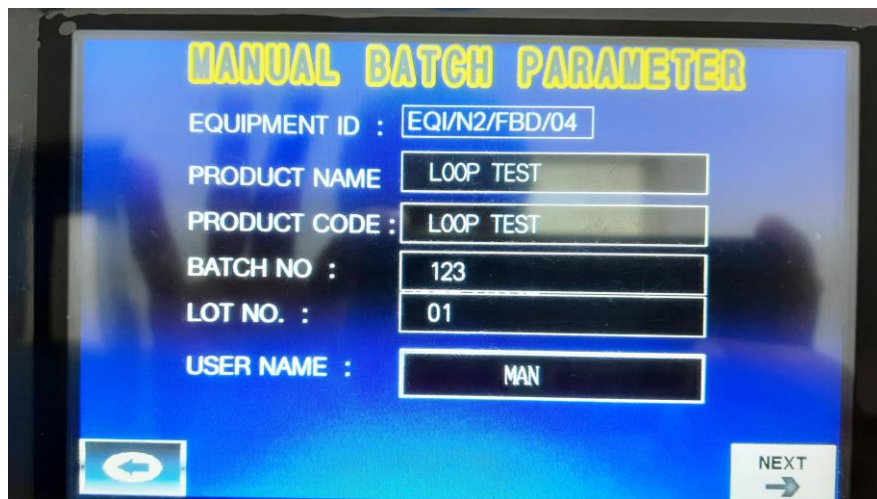
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5.5.2 After completion of machine setting press 'MANUAL'. Manual mode main screen will open.

5.5.3 Set manual Batch Parameter

- Product Name :
- Product Code :
- Batch No. :
- Lot No. :
- User Name :



5.5.4 And press NEXT on the right side of screen.

5.5.5 Place the FBD Bowl containing wet granules under the retarding chamber and fit it to the retarding chamber.



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5.5.6 Set the following parameters:

Manual mode ON/OFF

	SET	Actual	ALARM BAND
• Inlet temperature	: _____°C	_____°C	_____°C
• Exhaust temperature	: _____°C	_____°C	
• Inlet Damper Opening	: _____%	_____ %	
• RH Set	: _____%	_____ %	
• RH High Set	: _____%		
• RH Low Set	: _____%		
• Inlet temperature High set	: _____°C		
• Bed temperature Low set	: _____°C		

5.5.7 Press 'PREV' to open previous screen.

5.5.8 Press NEXT and set the Parameters

	SET
• Bed Temperature high set	: _____°C
• Bed Temperature Low set	: _____°C
• CFM	: _____
• Piston on time	: _____Sec
• Piston off time	: _____Sec
• Exhaust blower speed	: _____RPM
• Steam condensation On time	: _____sec

5.5.9 Press 'PREV' to open previous screen.

5.5.10 Press NEXT these options will appear



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- 5.5.11
- Bag UP/DOWN Print Header
  - Bowl to Chamber seal SOV ON/OFF Print ON/OFF
  - Upper Seal SOV ON/OFF Print interval \_\_\_\_\_MIN
  - Lower seal SOV ON/OFF
  - Exhaust Blower \_\_\_\_\_ RPM ON/OFF
  - Exhaust Damper ON/OFF
  - Shaking ON/OFF
  - Heating ON/OFF
  - RH ON/OFF
  - Lamp ON/OFF

5.5.12 Press EXIT to return to home Screen.

### 5.6 Auto Mode Operation:

- 5.6.1 For AUTO MODE Operation load the Required Recipe as per respective BMR as per procedure given in steps No. 5.4.2.
- 5.6.2 Press AUTO ON the home screen on the HMI
- 5.6.3 Press ON turn on the LAMP.
- 5.6.4 Following parameters are on screen:  
Auto cycle on time : \_\_\_\_\_min \_\_\_\_\_sec  
Auto cycle paused time : \_\_\_\_\_min \_\_\_\_\_sec  
Pro Temp \_\_\_\_\_°C
- 5.6.5 Press UP/DOWN to up or Down the Bag.
- 5.6.6 Down the Finger Bag assembly and Fit the finger bag in finger bag assembly and lift up the assembly.
- 5.6.7 Place the FBD Bowl containing wet granules under the retarding chamber and fit it to the retarding chamber by operating the lever on retarding chamber.
- 5.6.8 Press START to start a cycle of loaded Recipe.
- 5.6.9 Press STOP soft key to stop a running Cycle and RESET to Restart the cycle.
- 5.6.10 Press NEXT to see all the parameters set in the recipe.



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5.6.11 Press NEXT to see all the parameters set in the recipe.

**5.7 OPERATION (Without HMI modification):**

**5.7.1 Machine setting:**

5.7.1.1 Ensure 'CLEANED' label duly filled and signed is affixed on the equipment. Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet as per SOP no. PG/178 (Making entries in equipment usage and cleaning log sheet). Affix 'EQUIPMENT STATUS' label duly filled and signed on the equipment.

5.7.1.2 Turn main switch of PLC on 'ON' position.

5.7.1.3 Ensure the Compressed air pressure should be between 5.0 to 6.0 bars. Turn on the black selector switch to 'ON' position on the control panel.

5.7.1.4 Home Screen will appears as

LOGIN	MAN	AUTO	RECIPE	MAINT	LOGOUT
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5.7.1.5 Press LOGIN and enter password with the help of keypad on the MMI.

5.7.1.6 Touch 'MAIN MENU' on MMI. Main menu screen will appear. Touch 'LOGIN' ON MMI. Keypad will appear. Load correct password by pressing the alphanumeric keys then touch 'ENTER' for confirmation.

5.7.1.7 Touch 'MANUAL' on MMI. Manual mode main screen will appear.

5.7.1.8 Touch 'BAG UP/DOWN' on MMI. Pneumatic cylinder will come down.

5.7.1.9 Fix the FBT supporting ring at the fringes of finger bag and tight the rope.

5.7.1.10 Fix each finger one by one on the respective hook on the finger bag hanger.

5.7.1.11 Clamp the finger bag hanger on the pneumatic cylinder.

5.7.1.12 Attach the compressed air supply pipes to FBT supporting ring. Then tight the FBT ring to FBD bag with help of FBD bag rope. Touch "BAG UP" on MMI. When bag on position then touch bag seal on MMI.

5.7.1.13 Air Pressure of pressure gauge shall be maintained between 2.0 – 2.5 Kg/cm<sup>2</sup>. FBD by default stopped during process, if FBT pressure is not with in limit (2.0 – 2.5 Kg/cm<sup>2</sup>).

Note: Don't intervene the set value of FBT air pressure in between operation.

5.7.1.14 Touch 'BAG UP' on MMI. Pneumatic cylinder will start lifting up. Manually guide the guide rollers into the track.



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5.7.1.15 Place the FBD bowl containing material to be dried in between the lower plenum and retarding chamber and lock the clamps. Insert the product bed temperature sensor in the temperature sensor port of product container.

5.7.1.16 Touch 'SEAL' on MMI. Pressure reading on the PC pressure gauge shall increase to 2.0 to 2.5 bars.

5.7.1.17 Touch 'SEAL' on MMI. Pressure reading on the FBT pressure gauge shall increase to 2.0 to 2.5 bars.

**Note:** Turn OFF the main compressed air while hanging the FBD finger bag or Whenever the pneumatic cylinder is lifted lower.

### 5.7.2 **Recipe Edit / Load / Delete:**

5.7.2.1 Recipe can be edited / loaded / deleted in both auto and manual mode.

5.7.2.2 Press RECIPE soft key and set the following parameters

- Product Name : \_\_\_\_\_
- Equipment ID : \_\_\_\_\_
- Product Code : \_\_\_\_\_
- Batch No. : \_\_\_\_\_
- Lot No. : \_\_\_\_\_
- User Name : \_\_\_\_\_



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5.7.2.4 Press EDIT soft key and following parameters will appear on MMI.

- Air Dry Time : \_\_\_\_\_min
- Drying Time 1 : \_\_\_\_\_min
- Drying Time 2 : \_\_\_\_\_min
- Drying Time 3 : \_\_\_\_\_min
- Drying Time 4 : \_\_\_\_\_min
- Drying Time 5 : \_\_\_\_\_min
- Drying Time 6 : \_\_\_\_\_min
- Drying Time 7 : \_\_\_\_\_min
- Piston Off Time : \_\_\_\_\_sec
- Piston On Time : \_\_\_\_\_sec
- Cooling Time : \_\_\_\_\_min
- Shaking Interval Time : \_\_\_\_\_min
- Shaking duration Time : \_\_\_\_\_sec
- Piston down Time : \_\_\_\_\_sec
- Piston up Time : \_\_\_\_\_sec
- End Shaking Time : \_\_\_\_\_sec
- Exhaust Blower speed : \_\_\_\_\_RPM
- Steam Condensation On Time : \_\_\_\_\_sec
- Print Interval : \_\_\_\_\_min
- SET ALARM BAND
- Inlet Temperature : \_\_\_\_\_°C \_\_\_\_\_°C
- Inlet Temperature high : \_\_\_\_\_°C
- Exhaust Temperature : \_\_\_\_\_°C



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- DP Across HEPA High : \_\_\_\_\_” W/C
- Inlet Damper Opening : \_\_\_\_\_%
- RH Set : \_\_\_\_\_%
- RH low : \_\_\_\_\_%
- RH High : \_\_\_\_\_%

**Note:** In each run the actual time on print shown either equal or 1 to 2 sec less or more so that the time limit of each run shall be  $\pm 2$  sec.

5.7.2.5 Set the required parameters as specified in respective BMR.

5.7.2.6 Then press SAVE soft key to save a recipe (Save as new for new recipe if changes in parameter replace existing then press enter.

5.7.2.7 Load Product Name, Batch No., Equipment ID, Lot No., and User Name as per respective BMR.

5.7.2.8 Load Air Drying time, drying Time as per respective BMR.

5.7.2.9 Touch ‘Recipe edit’ on MMI. Keypad will open. Give suitable name or code for the recipe. Recipe will be get loaded in the PLC memory under given name or code.

5.7.2.10 To load already exist recipe Touch ‘LOAD’ on MMI. Stored recipe list will open. Select the recipe and touch ‘ESC’ on MMI. Warning ‘LOAD RECIPE XYZ’ (XYZ indicates name or code for a particular recipe). Touch ‘YES’ to load the selected recipe.

5.7.2.11 To delete already exist recipe touch ‘DELETE’ on MMI. Stored recipe list will open. Select the recipe and touch ‘ESC’ on MMI. Warning ‘DELETE RECIPE XYZ’ (XYZ indicates name or code for a particular recipe). Touch ‘YES’ to delete the selected recipe.

### 5.8 **Manual Mode Operation:**

5.8.1 Press ‘LOGIN’ soft key and enter the password.

5.8.2 After completion of machine setting press ‘MANUAL’ soft key. Manual mode main screen will open.

5.8.3 Set manual Batch Parameter

- Product code
- Batch No.,
- Operator code

5.8.4 And press NEXT soft key on the right side of screen.

5.8.5 Place the FBD Bowl containing wet granules under the retarding chamber and fit it to the retarding chamber.



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5.8.6 Set the following parameters:

	SET	ALARM BAND	HIGH SET
• Inlet temperature	: _____°C	_____°C	_____°C
• Exhaust temperature	: _____°C		_____°C
• Inlet Damper Opening	: _____%		_____%
• RH Set	: _____%		_____%
• RH High Set	: _____%		

5.8.7 Press 'PREV' soft key to open previous screen.

5.8.8 Press NEXT soft key and set the Parameters

	SET
• Inlet Temperature very high set Point	: _____°C
• Exhaust Temperature high set Point	: _____°C
• Bed Temperature low Set	: _____°C
• Bed Temperature high set	: _____°C
• DP across HEPA High	: _____" W/C

Press 'PREV' soft key to open previous screen.

5.8.9 Then Press NEXT soft key and Set

	SET
• Piston ON time	: _____sec
• Piston OFF time	: _____sec
• Exhaust Blower Speed	: _____RPM
• Steam condensation On time	: _____sec

as per respective BMR.

5.8.10 Press NEXT soft key these options will appear

• Bag	UP/DOWN
• Bowel to Chamber seal SOV	ON/OFF
• Upper Seal SOV	ON/OFF
• Lower seal SOV	ON/OFF
• Exhaust Blower	ON/OFF _____RPM

5.8.11 Press Up and Down keys and when curser blinks on ON/OFF, Press ENTER to ON or OFF. Touch 'PREV' soft key to open previous screen.





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5.8.12 Press NEXT soft key and options will appear as

- Exhaust Damper ON/OFF
- Shaking ON/OFF
- Heating ON/OFF
- RH ON/OFF
- Lamp ON/OFF

5.8.13 Press Up and Down keys and when cursor blinks on ON/OFF, Press ENTER to ON or OFF.

5.8.14 Press 'PREV' to open previous screen.

5.8.15 Press STEAM soft key and set the following parameters

5.8.16 Steam valve opening, Sampling Time, Input Filter, and Proportional Gain and press EXIT to return to home Screen.

**5.9 Auto Mode Operation**

5.9.1 For AUTO MODE Operation load the Required Recipe as per respective BMR as per procedure given in steps No. 5.4.2.

5.9.2 Press AUTO soft key on the home screen on the MMI

5.9.3 Press the DOWN soft key and press ENTER to ON the auto mode.

5.9.4 Press DOWN soft key and press ENTER to turn on the LAMP.

5.9.5 Following parameters are on screen:

Auto cycle on time : \_\_\_\_min \_\_\_\_sec

Auto cycle paused time : \_\_\_\_min \_\_\_\_sec

Pro Temp \_\_\_\_°C

- Bag: UP/DOWN

MAIN	ACK	START	STOP	RESET	NEXT
------	-----	-------	------	-------	------

5.9.6 Use DOWN soft keys and when cursor blinks on UP/DOWN Press ENTER soft key to up or Down the Bag.

5.9.7 Down the Finger Bag assembly and Fit the finger bag in finger bag assembly and lift up the assembly.

5.9.8 Place the FBD Bowl containing wet granules under the retarding chamber and fit it to the retarding chamber by operating the lever on retarding chamber.

5.9.9 Press START soft key to start a cycle of loaded Recipe.

5.9.10 Press STOP soft key to stop a running Cycle and RESET to Restart the cycle.

5.9.11 Press NEXT soft key to see all the parameters set in the recipe.



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- 5.10 **Product Unloading:**
- 5.10.1 Remove out the product bed temperature sensor.
  - 5.10.2 Open the Handle wheel lock and remove out the product container.
  - 5.10.3 Lift down the FBD bag.
  - 5.10.4 Remove individual finger of finger bag from the hooks of finger bag hanger.
  - 5.10.5 Remove the compressed air supply pipes from FBT supporting ring.
  - 5.10.6 Uptight the rope around FBT supporting ring and take out the finger bag.
  - 5.10.7 Turn main switch to 'OFF' position. MMI will turn OFF and reading on main air pressure will reduce to 0 bar and lock the control panel.
  - 5.10.8 Affix 'TO BE CLEANED' label duly filled and signed on the FBD and record the observations in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.11 **SFM (Solid Flow Monitor) Challenge Test:**
- 5.11.1 Replace the 'CLEANED' label and affix 'EQUIPMENT STATUS' label dully filled and signed on the equipment (In Case of cleaned equipment). or it can performed during "Type-B" cleaning.
  - 5.11.2 Take 200 grams of starch and put it in the FBD bowl.
  - 5.11.3 Start the FBD in Auto Mode at blower speed 1300 RPM.
  - 5.11.4 The FBD should be tripped as the starch comes in contact with SFM.
  - 5.11.5 After reset of SFM the machine can be start
  - 5.11.6 Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet) and in SFM Challenge test annexure-I (SFM Challenge Test).
  - 5.11.7 Again take 200 grams of starch and put it in the FBD bowl.
  - 5.11.8 Start the FBD in Manual mode at blower speed 1300 RPM.
  - 5.11.9 The FBD should be tripped as the starch comes in contact with SFM.
  - 5.11.10 After reset of SFM the machine can be start
  - 5.11.11 Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet) and in SFM Challenge test annexure-I (SFM Challenge Test).
  - 5.11.12 After "SFM Challenge Test", Type B cleaning should be performed. And the same should be recorded in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
  - 5.11.13 If challenge test not complies then inform to production head and maintenance head, and after rectification again perform the SFM challenge test.



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5.11.14 SFM sensor cleaning is to be performed at the end of week by maintenance personnel with internal communication from production to maintenance department and record the details in Annexure III (SFM sensor weekly cleaning record).

5.11.15 **Frequency:** First week of the Month.

### 6.0 ABBREVIATION (S):

- 6.1 FBD : Fluidized Bed Drier
- 6.2 IPA : Iso Propyl Alcohol
- 6.3 V/V : Volume/Volume
- 6.4 MMI : Man Machine Interface
- 6.5 HEPA : High efficiency particulate air
- 6.6 PC : Product Container
- 6.6 DP : Differential Pressure
- 6.7 FBT : Finger Bag Tube
- 6.8 FC : Flow Control
- 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.
- 7.5 SOP: Cleaning And Utilization of FBD Finger Bag / RMG Filter Bag
- 7.6 SOP: Cleaning Verification

### 8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	SFM (Solid Flow Monitor) Challenge Test		Logbook
Annexure-II	Cleaning checklist of FBD (Bectochem)		Logbook
Annexure-III	SFM sensor weekly cleaning record		Logbook

### 9.0 DISTRIBUTION (S):

- 9.1 **Master Copy** : Quality Assurance



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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
01	00		NEW SOP	NA	NA





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### ANNEXURE II CLEANING CHECKLIST OF FBD (BECTOCHEM)

Name of the Equipment		FLUIDIZED BED DRYER	
Equipment ID. No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity performed	
1.	Shake the finger bag in manually mode to dedust.		
2.	Remove the remainants of the previous batch from the equipment and the area with vacuum cleaner.		
3.	Allow sucking the powder attached with the wall and return raiser using vacuum cleaner.		
4.	Bring down the finger bag by operating the finger bag handle towards lower side.		
5.	Remove the bag from the finger holding ring and clean the bag.		
6.	Pull out the product container bowl; dismantle the view glass (1 nos.) of product container bowl and viewing glass (2 nos.) of bag chamber.		
7.	Scrub the bag chamber, explosion chamber and finger bag holder ring and view glasses with gasket, inflated gasket (2 nos.), inflated tube ring with a nylon scrubber using purified water from inside and outside to remove any adhered material.		
8.	Clean the Inlet Duct and Outlet Duct prior to dampers with high pressure jet cleaner and cleanliness shall be ensured up to maximum accessible area.		
9.	Use the ladder to clean the outer surface bag chamber.		
10.	Rinse all the above parts with 130-150 liters of purified water.		
11.	Scrub the product container bowl and trolley with a nylon scrubber using purified water.		
12.	Remove the gasket Dutch weave sieve and the supporting plate.		
13.	Place the sieve in a horizontal position. Scrub the sieve with a nylon scrubber using 30-40 liters of purified water.		
14.	Scrub the supporting plate with a nylon scrubber using purified water.		



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S.No.	Activity	Activity performed
15.	Rinse the product container bowl, sieve and supporting plate with 40-50 liters of Purified water.	
16.	Place the sieve and the supporting plate on a clean S.S. pallet.	
17.	Reassemble the sieve and the supporting plate.	
18.	Scrub the outside of the FBD, supporting arms inlet air duct and the inlet chamber with a nylon scrubber using 40-50 liters of purified water.	
19.	Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.	
20.	Clean the utility cables limit switches and control panel with a dry lint free duster.	
21.	Reassemble the view glasses of product container of bowl and bag chamber.	
22.	Fix the duly cleaned finger bag on the finger bag holder ring and position the finger bag.	
23.	Assemble the FBD and operate the FBD as per the SOP No.PG/012, at an inlet temperature of 70-80°C for 30 to 40 minutes to dry the sieve and finger bag.	
24.	Remove the finger bag and transfer it to the granulation spare area.	
25.	Rinse the bag chamber, explosion chamber and view glasses with 40-50 liters of purified water.	
26.	Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.	
27.	Wipe all the above parts with 70% v/v IPA solution.	

**Checked By (Prod.)**  
**Sign/Date**

**Verified By (QA)**  
**Sign/Date**

**Note:** Put '√' mark if activity is performed and put 'X' if activity is not performed.

