



# 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 30 kg (Make: Anchor Mark)	<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 (GM 250 S). To lay down a procedure for cleaning and operation of Fluid Bed Dryer 30 Kg (Make: Anchor Mark).

### 2.0 SCOPE:

- 2.1. This procedure is applicable to the cleaning and Operation procedure of Fluid Bed Dryer 30 Kg (Make: Anchor Mark) 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.**
  - 5.1.1. Remove “UNDER PROCESS” label and affix dully filled “UNDER CLEANING” label to the machine.
  - 5.1.2. Enter the cleaning start time in equipment usage log sheet SOP (Making entries in equipment usage and cleaning and log sheet)
  - 5.1.3. Manually close the inlet valve.
  - 5.1.4. Shake the finger bag in manual mode to dedust.
  - 5.1.5. Remove the ruminants of the previous batch from the equipment and the area with vacuum cleaner.
  - 5.1.6. Allow sucking the powder attached with the wall and return riser using vacuum cleaner.
  - 5.1.7. Clean the plenum, bag chamber, inlet and outlet air ducts from outside using a dry clean lint free duster.
  - 5.1.8. Clean the product container bowl with dry lint free cloth to remove any leftover material.
  - 5.1.9. Affix dully filled status label on RMG as “CLEANED” with date and signature of Production Officer verified by QA officer.



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- 5.1.10. Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning and log sheet)
- 5.2. **“TYPE B” CLEANING-This is a cleaning procedure for Changeover of product with different actives / color / descending potency or after maintenance of contact parts.**
  - 5.2.1. Follow the procedure from step 5.1.1 to 5.1.5.
  - 5.2.2. Using PLC bring down the finger bag as follows:
    - 5.2.2.1. Open Manual mode main screen.
    - 5.2.2.2. Touch ‘BOWL SEAL’ on MMI. Bowl sealing gasket will unseal the bowl.
    - 5.2.2.3. Touch ‘BAG SEAL’ on MMI. Bag sealing gasket will unseal the finger bag tube.
    - 5.2.2.4. Remove out the product bed temperature sensor.
    - 5.2.2.5. Open the Clamps and remove out the product container.
    - 5.2.2.6. Touch ‘BAG DOWN’ on MMI. Bag ring holding rope will come down.
  - 5.2.3. Remove individual finger of finger bag from the hooks of finger bag hanger.
  - 5.2.4. Remove the bag from the finger holding ring and cleaning shall be done as per SOP “Cleaning and Utilization of FBD/FBP Finger Bag / RMG Filter Bag / Air Jet Micronizer Filter Bag”.
  - 5.2.5. Dismantle the view glass (1 nos.) of product container bowl and viewing glass (2 nos.) of bag chamber.
  - 5.2.6. Scrub the bag chamber, explosion chamber and finger bag holder ring and view glasses with gasket, inflated gasket (2 nos.), and inflated tube ring with a nylon scrubber using 50 liters of purified water from inside and outside to remove any adhered material.
  - 5.2.7. 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.
  - 5.2.8. Use the ladder to clean the outer surface of bag chamber.
  - 5.2.9. Rinse all the above parts with 50 liters of purified water using high pressure jet cleaner.
  - 5.2.10. Scrub the product container bowl and trolley with a nylon scrubber using 60 liters of purified water.
  - 5.2.11. Remove the gasket Dutch weave sieve and the supporting plate.
  - 5.2.12. Place the sieve in a horizontal position. Scrub the sieve with nylon scrubber with 60 liters of purified water using high pressure jet cleaner.
  - 5.2.13. Scrub the supporting plate with a nylon scrubber using 20 liters of purified water using high pressure jet cleaner.
  - 5.2.14. Rinse the product container bowl, sieve and supporting plate with 60 liters of purified water.
  - 5.2.15. Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate



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- 5.2.16. Scrub the out side of the FBD, supporting arms inlet air duct and the inlet chamber with a nylon scrubber using 40-50 liters of purified water with high pressure jet cleaner.
- 5.2.17. Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-15 liters of purified water using high pressure jet cleaner.
- 5.2.18. Clean the utility cables limit switches and control panel with a dry lint free duster.
- 5.2.19. Reassemble the view glasses of product container of bowl and bag chamber.
- 5.2.20. Put the cleaned FBD finger bag and RMG filter bag in FBD bowl.
- 5.2.21. 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
- 5.2.22. Rinse the FBD bowl, bag chamber, explosion chamber and view glasses with 25-35 liters of purified water.
- 5.2.23. Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.
- 5.2.24. Wipe all the above parts with 70% v/v IPA solution.
- 5.2.25. Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.26. Record the cleaning completion time in equipment usage log sheet as per SOP. (Making entries in equipment usage and cleaning and log sheet).
- 5.2.27. Record the cleaning checklist Annexure-I (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 seven days then follow the procedure of type – B cleaning.
- 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.
- 5.3.3. Cleaning (Dedusting) of machine with vacuum cleaner and dry lint free cloth) is applicable in case of at the end of working day.

**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 than type B cleaning shall be performed before use.



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### 5.4. OPERATION:

#### 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. Affix 'UNDER PROCESS' label duly filled and signed on the equipment.

5.4.1.2. Turn Control switch to ON position.

5.4.1.3. Following home screen will appear:



5.4.1.4. Touch the LOGIN on MMI for Login to the system. Use desired login ID and respective password as per the requirement.





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5.4.1.5. There are 4 password levels in the system User1, User2, User3 and Admin.

User Level	User Rights
User1	Can Start/Stop Machine
User2	Can Start/Stop Machine, Can Edit Product Name/Batch No/Lot No/ Can Load the Recipe
User3	Can Start/Stop Machine, Can Edit Product Name/Batch No/Lot No/ Can Load/Edit the Recipe
Admin	Can Start/Stop Machine, Can Edit Product Name/Batch No/Lot No/ Can Load/Edit the Recipe, Can change the internal setting of the machine.

5.4.1.6. After login select Operation and following screen will appear:



5.4.1.7. Select 'MANUAL ENABLE' to enable the manual mode, following screen will appear:





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5.4.1.8. Now select 'MANUAL ACTION' following screen will appear:



5.4.1.9. Touch 'BAG DOWN' on MMI. Rope will come down. Rope of finger bag holding ring integrity (damage) should be checked before start of operation and after completion of operation.

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

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

5.4.1.12. Fit the finger bag hanger on the rope.

5.4.1.13. Attach the compressed air supply pipes to FBT supporting ring.

5.4.1.14. Touch on "BAG UP" MMI, bag holding ring will start lifting up. Manually guide the guide rollers into the track.

5.4.1.15. Touch on "BAG SEAL" to seal the finger bag gasket.

5.4.1.16. 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.

5.4.1.17. Touch on "BOWL SEAL" Pressure reading on the PC pressure gauge shall increase to 2.5 to 3.5 bar.


5.4.1.18. Touch Home  on MMI and home screen will appear.

### 5.4.2. Recipe Edit / Load / Delete

5.4.2.1. Recipe can be edited / loaded / deleted in auto mode.

5.4.2.2. Touch 'RECIPE' on MMI. Following recipe main screen will appear.

5.4.2.3. Enter product name, Equipment ID, Batch No, lot No, user, Blower speed in following screen.

5.4.2.4. Click on  for next screen.



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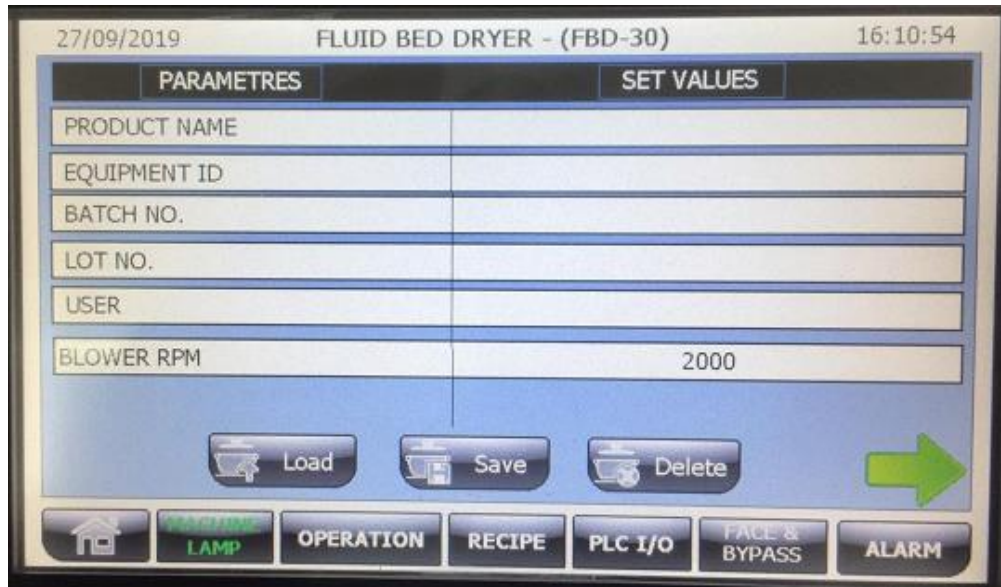
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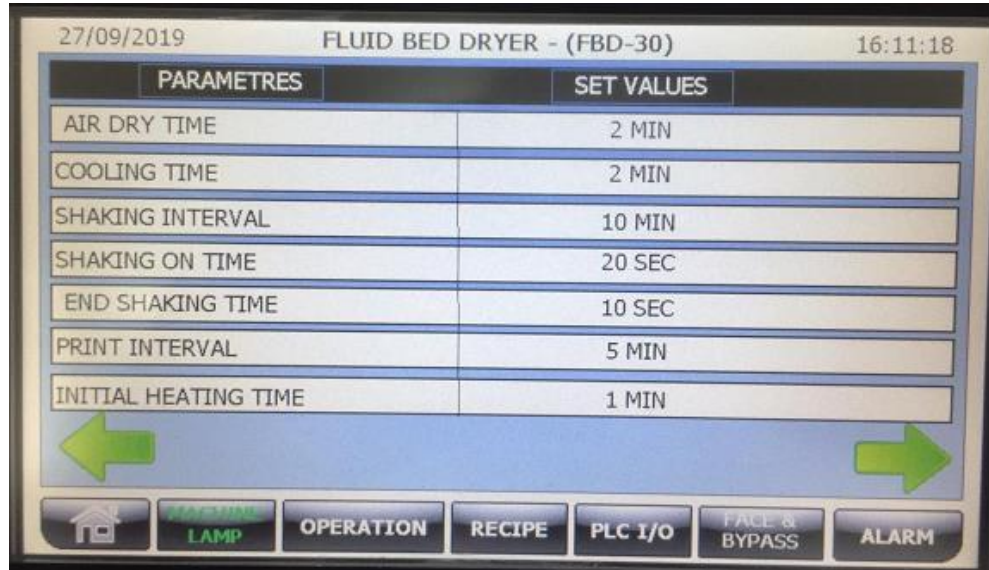
**Review Date:**

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5.4.2.5. Following screen will appear.



5.4.2.6. Enter air drying time 'cooling time, shaking interval, shaking on time, End shaking time, print interval, Initial heating time as per respective batch record.

5.4.2.7. Click on  for next screen following screen will open.



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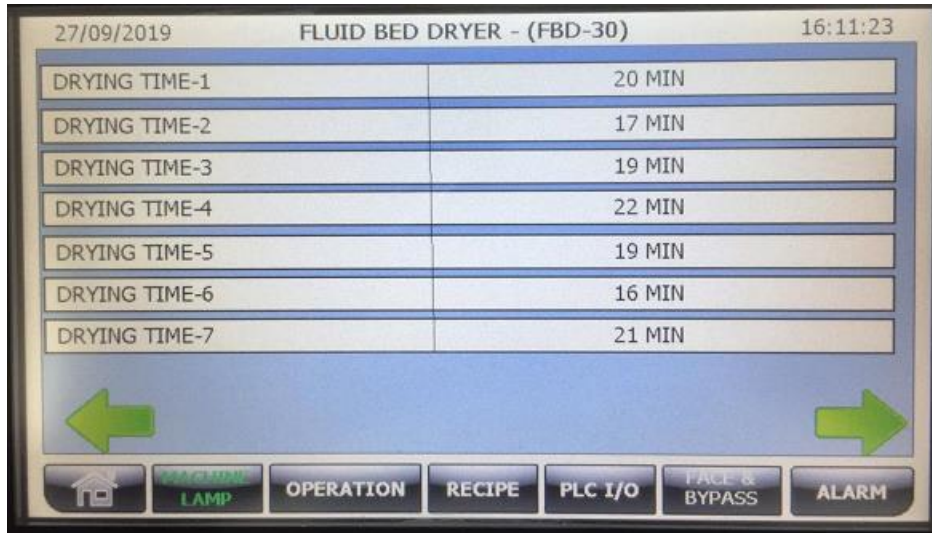
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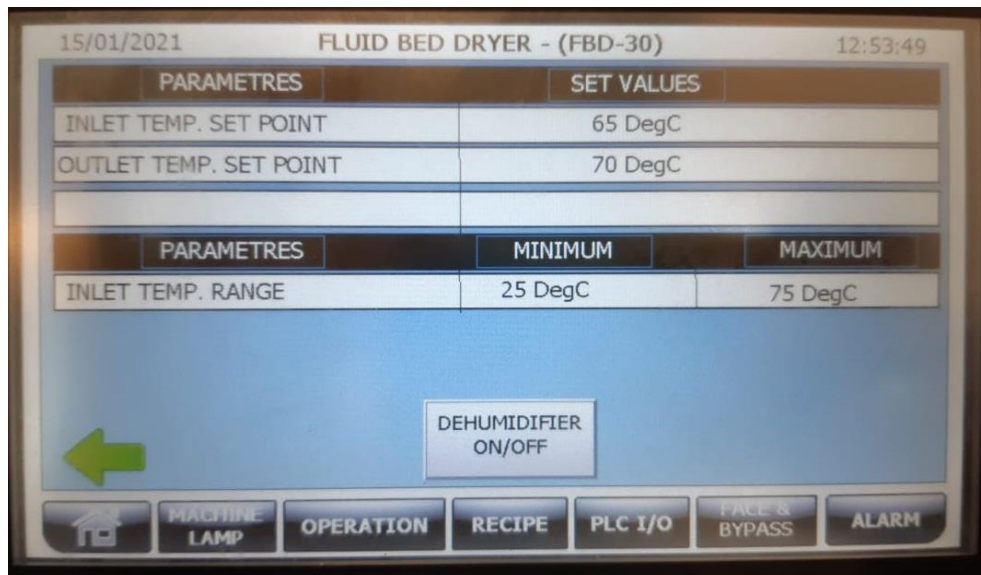
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5.4.2.8. Enter drying time in all cycle of drying from drying time 1 to drying time 7 as per requirement.

5.4.2.9. Touch on dehumidifier ON/OFF button to start the dehumidifier.

5.4.2.10. Load the parameters as per respective product BMR and touch  $\Rightarrow$  for next screen.



5.4.2.11. After updating the parameters from respective BMR come on first screen by click on  $\Rightarrow$  ' and SAVE RECIPE' with product name.

5.4.2.12. To load already exist recipe Touch 'LOAD' on MMI. Stored recipe list will open.





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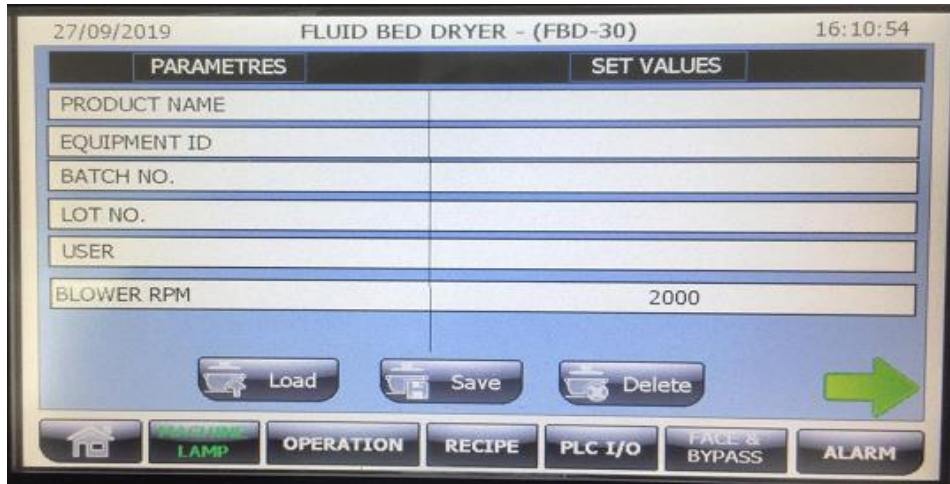
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- 5.4.2.13. Select the recipe on MMI. Warning “Recipe” XYZ already Exist do you want to replace it. (XYZ indicates name or code for a particular recipe). Touch ‘YES’ to load the selected recipe.



- 5.4.2.14. After saving the recipe touch the operation.

### 5.4.3. Manual Mode Operation:

- 5.4.3.1. After login select Operation and following screen will appear:

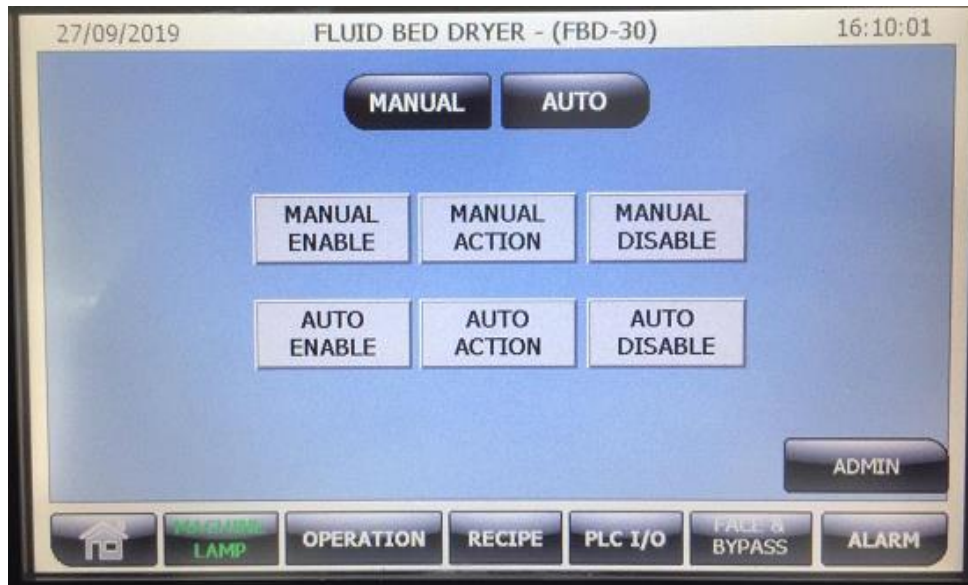


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5.4.3.2. Select 'MANUAL ENABLE' to enable the manual mode, following screen will appear:



5.4.3.3. Now touch on 'MANUAL ACTION' following screens will appear:



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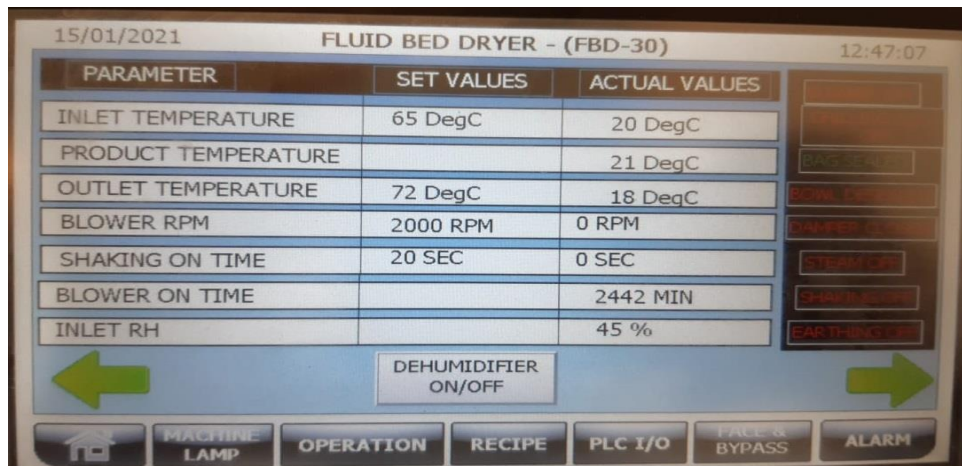
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5.4.3.4. Click on  $\Rightarrow$  next screen will appear.



5.4.3.5. Set the parameter as per respective batch manufacturing record.

5.4.3.6. Click on  $\Rightarrow$  next screen will open.



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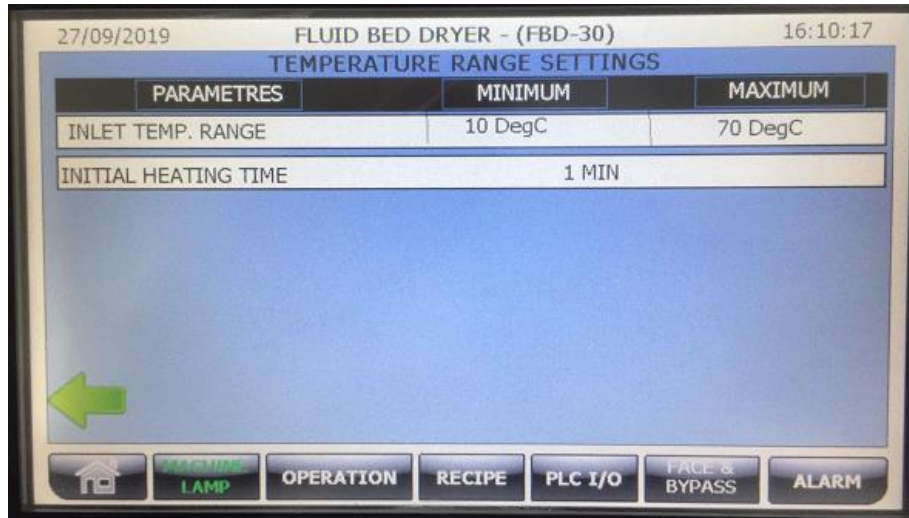
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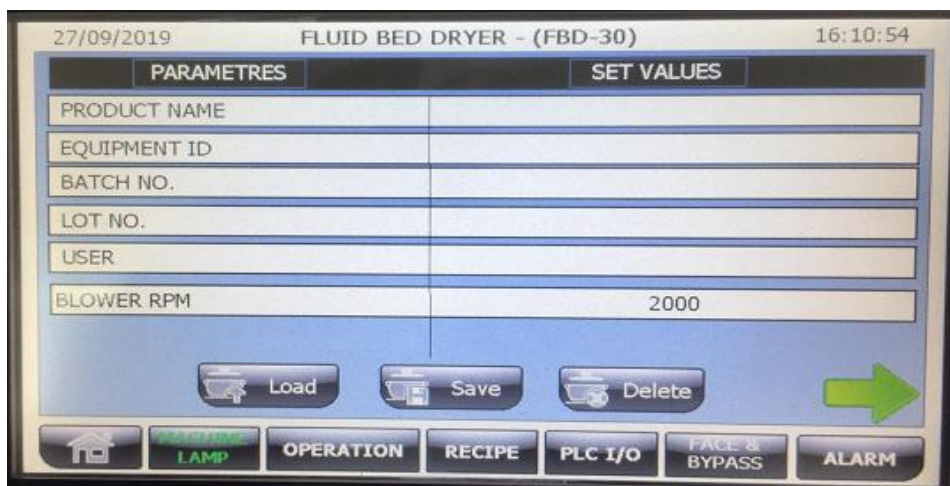
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- 5.4.3.7. Set the parameter as per respective batch manufacturing record.
- 5.4.3.8. Touch on dehumidifier ON/OFF button to start the dehumidifier.
- 5.4.3.9. After setting the parameter go on first screen of manual mode and click on blower to start the machine.

#### 5.4.4. AUTO MODE:

- 5.4.4.1. Load the recipe by click on 'LOAD' on MMI. Stored recipe list will open. Select the recipe. Change the batch no, user name and then click on save to save the details.



- 5.4.4.2. Click on load shown below the recipe list.



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5.4.4.3. After login select Operation and following screen will appear



5.4.4.4. Select 'AUTO ENABLE' to enable the auto mode, following screen will open.



5.4.4.5. Now click on 'AUTO ACTION' following screens will appear:



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- 5.4.4.6. Now click on START to start the machine.
- 5.4.4.7. Process will run as per set parameters and stop automatically on completion of each cycle.
- 5.4.4.8. After completion of each run cycle start the machine by click on start if required.
- 5.4.4.9. **Note:** Before start of machine ensure that the printer is ready to print.
- 5.4.5. **Product Unloading:**
  - 5.4.5.1. Click on auto disable “MANUAL” “AUTO” screen will open.
  - 5.4.5.2. Click on manual enable then manual action the manual screen will open.
  - 5.4.5.3. Touch ‘BOWL SEAL’ on MMI. The sealing gasket of bowl become deflated.
  - 5.4.5.4. Touch ‘BAG SEAL’ on MMI. The sealing gasket of finger bag ring become deflated.
  - 5.4.5.5. Remove out the product bed temperature sensor.
  - 5.4.5.6. Open the Clamps and remove out the product container.
  - 5.4.5.7. Touch ‘BAG LIFT LOWER’ on MMI. Pneumatic cylinder will come down.
  - 5.4.5.8. Remove individual finger of finger bag from the hooks of finger bag hanger.
  - 5.4.5.9. Remove the compressed air supply pipes from FBT supporting ring.
  - 5.4.5.10. Uptight the rope around FBT supporting ring and take out the finger bag.
  - 5.4.5.11. 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.
  - 5.4.5.12. 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 and log sheet).



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### 5.5. SFM (Solid Flow Monitor) Challenge Test and Cleaning:

- 5.5.1. Replace the 'CLEANED' label and affix 'UNDER PROCESS' label dully filled and signed on the equipment (In Case of cleaned equipment). Or it can perform during "Type-B" cleaning.
- 5.5.2. Take 200 grams of starch and put it in the FBD bowl.
- 5.5.3. Start the FBD in Manual Mode with Blower 2000 to 2200 RPM.
- 5.5.4. The FBD should be tripped as the starch comes in contact with SFM.
- 5.5.5. After reset of SFM the machine can be started.
- 5.5.6. Record the activity in equipment usage log sheet as per SOP and in SFM Challenge test Annexure-I. (Cleaning checklist of FBD).
- 5.5.7. Again take 200 grams of starch and put it in the FBD bowl.
- 5.5.8. Start the FBD in Auto Mode with Blower 2000 to 2200 RPM.
- 5.5.9. The FBD should be tripped as the starch comes in contact with SFM.
- 5.5.10. After reset of SFM the machine can be start.
- 5.5.11. Record the activity in equipment usage log sheet as per SOP and in SFM Challenge test Annexure-II SFM (Solid Flow Monitor) challenge test.
- 5.5.12. After "SFM Challenge Test", Type B cleaning should be performed. And the same should be recorded in equipment usage log sheet as per SOP.
- 5.5.13. If 'SFM Challenge Test' not complies then inform to Production head and Maintenance head and after rectification again perform the 'SFM Challenge Test' and record the same in equipment usage log book.
- 5.5.14. **Frequency:** First week of the Month
- 5.5.15. SFM sensor cleaning is to be performed at the end of every week by maintenance personnel with internal communication from production to maintenance department and Annexure-III (SFM sensor Cleaning record) is to be updated after every cleaning by maintenance personnel.

### 6.0 ABBREVIATION (S):

- 6.1. FBD : Fluidized Bed Drier
- 6.2. IPA : Iso Propyl Alcohol
- 6.3. QA : Quality Assurance
- 6.4. SS : Stainless Steel
- 6.5. SOP : Standard Operating Procedure
- 6.6. v/v : Volume/Volume
- 6.7. BMR : Batch Manufacturing Record
- 6.8. MMI : Man Machine Interface



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- 6.9. HEPA : High efficiency particulate air
- 6.10. PC : Product Container
- 6.11. DP : Differential Pressure
- 6.12. FBT : Finger Bag Tube
- 6.13. FC : Flow Control

### 7.0 REFERENCE (S):

- 7.1. SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2. SOP: Cleaning and utilization of FBD finger bag and RMG filter bag.

### 8.0 ANNEXURE (S)

Annexure No.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning checklist of FBD		Log Book
Annexure II	SFM (Solid Flow Monitor) Challenge Test		Log Book
Annexure III	SFM Sensor Cleaning record		Log Book

### 9.0 DISTRIBUTION:

- 9.1. **Master Copy:** Quality Assurance
- 9.2. **Controlled Copy (S):** Production (01), Quality Assurance (01)
- 9.3. **Reference Copy (S):** Production Department (01)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
1.	00		New SOP	NA	





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### ANNEXURE I

#### CLEANING CHECKLIST OF FBD 30 KG (ANCHORMARK)

Name of the Equipment		Fluidized Bed dryer (30 Kg ANCHORMARK)	
Equipment I.D. 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.	Using PLC bring down the finger bag.		
5.	Remove the bag from the finger holding ring and cleaning shall be done as per SOP "Cleaning and Utilization of FBD/FBP Finger Bag / RMG Filter Bag / Air Jet Micronizer Filter 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.), and inflated tube ring with a nylon scrubber using 50 liters of 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 of bag chamber.		
10.	Rinse all the above parts with 50 liters of purified water.		
11.	Scrub the product container bowl and trolley with a nylon scrubber using 60 liters of 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 nylon scrubber with 60 liters of purified water.		
14.	Scrub the supporting plate with a nylon scrubber using 20 liters of purified water.		
15.	Rinse the product container bowl, sieve and supporting plate with 60 liters of purified water.		
16.	Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate.		



# 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 30 kg (Make: Anchor Mark)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

17.	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.	
18.	Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-15 liters of purified water.	
19.	Clean the utility cables limit switches and control panel with a dry lint free duster.	
20.	Reassemble the view glasses of product container of bowl and bag chamber.	
21.	Put the cleaned FBD finger bag and RMG filter bag in FBD bowl.	
22.	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.	
23.	Rinse the FBD bowl, bag chamber, explosion chamber and view glasses with 25-35 liters of purified water.	
24.	Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.	
25.	Wipe all the above parts with 70% v/v IPA solution.	
26.	Replace the "TO BE CLEANED" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.	

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

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

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



