



# 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 (GM 250 HW)	<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 HW).

### 2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Fluid Bed Dryer (GM 250 HW) located in manufacturing area.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation of Fluidized Bed Dryer

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 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 remainants 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.



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- 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 leftover material.
- 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 / color / 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.
- 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 Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)
- 5.2.10 Scrub the product container bowl and trolley with a nylon scrubber using 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 a nylon scrubber using 30-40 liters of purified water.



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- 5.2.13 Scrub the supporting plate with a nylon scrubber using purified water.
- 5.2.14 Rinse the product container bowl, sieve and supporting plate with 40-50 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.
- 5.2.16 Clean the FBD (Outer surface, inner surface, and FBD bowl) with sufficient quantity of purified water with the help of High Pressure Jet Cleaner to remove any particles/residue or any traces.
- 5.2.17 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.
- 5.2.18 Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.
- 5.2.19 Clean the utility cables limit switches and control panel with a dry lint free duster.
- 5.2.20 Reassemble the view glasses of product container of bowl and bag chamber.
- 5.2.21 Put the cleaned FBD finger bag and RMG filter bag in FBD bowl.
- 5.2.22 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.
- 5.2.23 Rinse the FBD bowl, bag chamber, explosion chamber and view glasses with 40-50 liters of purified water.
- 5.2.24 Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.
- 5.2.25 Wipe all the above parts with 70% v/v IPA solution.
- 5.2.26 Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.27 Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet.).
- 5.2.28 Record the cleaning activity in Annexure II.

### 5.3 Frequency:



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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 as per SOP (Cleaning Verification).

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 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.).

### 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 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 Open the lock of control panel. Turn main switch to 'MANUAL' or 'AUTO' position. Reading on main air pressure gauge will start increasing and opening screen will appear on MMI. Ensure the Compressed air pressure should be NLT 5 bar.

5.4.1.3 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.

5.4.1.4 Touch 'MANUAL' on MMI. Manual mode main screen will appear and shows

PC seal vent	-	Auto
FBT seal vent	-	MANL
BAG lift lower	-	MAIN MENU

5.4.1.5 Touch 'BAG LIFT LOWR' on MMI. Pneumatic cylinder will come down.



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- 5.4.1.6 Fix the FBT supporting ring at the fringes of finger bag and tight the rope.
- 5.4.1.7 Fix each finger one by one on the respective hook on the finger bag hanger.
- 5.4.1.8 Clamp the finger bag hanger on the pneumatic cylinder.
- 5.4.1.9 Attach the compressed air supply pipes to FBT supporting ring.
- 5.4.1.10 Touch 'BAG LIFT LOWR' on MMI. Pneumatic cylinder will start lifting up. Manually guide the guide rollers into the track.
- 5.4.1.11 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.
- 5.4.1.12 Touch 'PC SEAL VENT' on MMI. Pressure reading on the PC pressure gauge shall increase to 2.0 to 2.5 bars.
- 5.4.1.13 Touch 'FBT SEAL VENT' on MMI. Pressure reading on the FBT pressure gauge shall increase to 2.0 to 2.5 bars.
- 5.4.1.14 Touch 'MAIN MENU' on screen. Main menu screen will appear.

**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 be edited / loaded / deleted in both auto and manual mode.
- 5.4.2.2 Touch 'RECIPE' on MMI. Recipe main screen will appear.
- 5.4.2.3 Touch 'EDIT' on MMI. Recipe edit main screen will open with following menu: 'Program No., Product Name, Batch No., Lot No., Operator Code, FBD Tag No., Product Code, Batch size, Manufacturing Date, Expiry Date'.
- 5.4.2.4 Load Product Name, Batch No., Lot No., FBD Tag No., Product Code, Batch size, Manufacturing Date, Expiry Date as per respective BMR.
- 5.4.2.5 Touch 'NEXT' on MMI. 'RECIPE EDIT-1' screen will open with following menu: 'Process Time, Air Dry Time, Spray Time, Spray OFF Time, Spray ON Time, Shaking Interval, Shaking Duration, Piston Up, Piston Down, Cooling Time, End Shaking Time, Piston Up, Piston Down'.
- 5.4.2.6 Load Process Time, Air Dry Time as per respective BMR.



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5.4.2.7 Touch 'Edit – 2' on MMI. 'RECIPE EDIT-2' screen will open with following menu: 'Inlet Temperature, Outlet Temperature, Inlet High, Spray Temperature, RH Set Point, print Interval, DP across HEPA Set, DP across FBT set, Spray Pump speed'.

5.4.2.8 Load inlet temperature, outlet temperature, inlet high temperature, RH set point, print Interval, DP across HEPA, and DP across finger bag by pressing Load on MMI

5.4.2.9 Touch 'LOAD' on MMI. Recipe load screen will open and it displays the loaded process parameter's details.

5.4.2.10 Touch 'STORE' 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.

5.4.2.11 Touch 'MAIN SCREEN' on MMI. Recipe main screen will open.

5.4.2.12 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.

5.4.2.13 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.

### 5.5 Manual Mode Operation:

5.5.1 Ensure main switch of control panel is at 'Manual' position.

5.5.2 Touch 'LOGIN' and enter the password.

5.5.3 After completion of machine setting touch 'MANUAL' on screen. Manual mode main screen will open.

5.5.4 Touch 'MAN-1' on MMI. Man-1 screen will open.

5.5.5 Touch 'BLOWER' on MMI. Blower will start. Touch Inlet Damper and Hot Water to start.

5.5.6 Touch 'BYPASS DAMPER' on MMI. Bypass Damper screen will open. Current status of the inlet air temperature, outlet air temperature, product bed temperature, air velocity and DP across HEPA and finger bag will also displayed on this screen. Set the bypass damper ON/OFF % depending on the inlet air, outlet air and product bed temperature. Touch 'BYPASS DAMPER' ON MMI to ON / OFF the by pass damper.

5.5.7 Touch 'PREV' to open previous screen.

5.5.8 At the end of operation touch 'BLOWER' on MMI. Blower will stop.



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- 5.5.9 Touch 'MAN' on MMI. Manual mode main screen will open.
- 5.5.10 In case of "AUTO" mode failure during batch processing, machine can be run in "MANUAL" mode to Complete the batch by intimating to QA and Engineering department.

### 5.6 Auto Mode Operation:

- 5.6.1 Ensure main switch of control panel is at 'AUTO' position.
- 5.6.2 Touch 'LOGIN' and enter the password.
- 5.6.3 Touch 'AUTO' on MMI. Auto selected screen will open and it displays inlet, outlet and product bed temperature.
- 5.6.4 Touch 'START' to start the process on MMI.
- 5.6.5 Touch 'HOT WATER' on MMI. Hot water setting screen will open. Set Hot water ON and OFF time.
- 5.6.6 Touch 'PREV' on MMI. Auto selected screen will open.
- 5.6.7 Touch 'IND' on MMI. Next screen will open and it displays current process status for example 'Air Dry Time Started'. Set and actual values for Inlet, outlet and product bed temperature, DP across HEPA and finger bag and air velocity will also displayed on screen.
- 5.6.8 Touch 'IND 2' on MMI. Screen will show set and actual RH and % of FC damper opening, set and actual % opening of the by pass damper.
- 5.6.9 Touch 'MAN' on MMI. Auto selected main screen will open.
- 5.6.10 Process will run as per set parameters and stops automatically on completion of cycle.
- 5.6.11 Touch 'MAIN SCREEN' on MMI. Main screen will open. Touch 'LOGOUT' on MMI. 'OK, you are Logged Out' message will display on MMI.

### 5.7 Product Unloading:

- 5.7.1 Open Manual mode main screen.
- 5.7.2 Touch 'PC SEAL VENT' on MMI. Pressure reading on the PC pressure gauge shall decrease to 0 bar.
- 5.7.3 Touch 'FBD SEAL VENT' on MMI. Pressure reading on the FBT pressure gauge shall decrease to 0 bar.
- 5.7.4 Touch 'MAIN MENU' on screen. Main menu screen will appear.
- 5.7.5 Touch 'OPENING SCREEN' on MMI. Opening screen will open.
- 5.7.6 Remove out the product bed temperature sensor.
- 5.7.7 Open the Clamps and remove out the product container.



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- 5.7.8 Touch 'FBD LIFT LOWR' on MMI. Pneumatic cylinder will come down.
- 5.7.9 Remove individual finger of finger bag from the hooks of finger bag hanger.
- 5.7.10 Remove the compressed air supply pipes from FBT supporting ring.
- 5.7.11 Uptight the rope around FBT supporting ring and take out the finger bag.
- 5.7.12 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.
- 5.7.13 Affix 'UNDER CLEANING' 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.).

### 5.8 SFM (Solid Flow Monitor) Challenge Test

- 5.8.1 Replace the 'CLEANED' label and affix 'EQUIPMENT STATUS' label duly filled and signed on the equipment (In Case of cleaned equipment). Or it can perform during "Type-B" cleaning.
- 5.8.2 Take 200 grams of starch and put it in the FBD bowl.
- 5.8.3 Start the FBD in Auto Mode with 20% exhaust flap open.
- 5.8.4 The FBD should be tripped as the starch comes in contact with SFM.
- 5.8.5 After reset of SFM the machine can be start.
- 5.8.6 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 (Solid Flow Monitor) Challenge Test).
- 5.8.7 Again take 200 grams of starch and put it in the FBD bowl.
- 5.8.8 Start the FBD in Manual Mode with 20% exhaust flap open.
- 5.8.9 The FBD should be tripped as the starch comes in contact with SFM.
- 5.8.10 After reset of SFM the machine can be start.
- 5.8.11 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 (Solid Flow Monitor) Challenge Test).
- 5.8.12 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.).
- 5.8.13 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.





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5.8.14 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).

5.8.15 **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
- 6.7 DP : Differential Pressure
- 6.8 FBT : Finger Bag Tube
- 6.9 FC : Flow Control
- 6.10 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 Verification

### 8.0 ANNEXURE (S)

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	SFM (Solid Flow Monitor) Challenge Test		Log Book
Annexure II	Cleaning Checklist of FBD (GM250 HW)		Log Book
Annexure III	SFM sensor weekly cleaning record		Log Book



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### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S):** Production Department (02)/ Quality Assurance (01)
- 9.3 **Reference Copy (S) :** Production Department (01)/ Utility (01)

### 10.0 REVISION HISTORY

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





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### ANNEXURE II

#### CLEANING CHECKLIST OF FBD (GM250 HW)

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.	Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz.		
12.	Scrub the product container bowl and trolley with a nylon scrubber using purified water.		
13.	Remove the gasket Dutch weave sieve and the supporting plate.		
14.	Place the sieve in a horizontal position. Scrub the sieve with a nylon scrubber using 30-40 liters of purified water.		
15.	Scrub the supporting plate with a nylon scrubber using purified water.		
16.	Rinse the product container bowl, sieve and supporting plate with 40-50 liters of Purified water.		



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S.No.	Activity	Activity performed
17.	Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate.	
18.	Clean the FBD (Outer surface, inner surface, and FBD bowl) with sufficient quantity of purified water with the help of High Pressure Jet Cleaner to remove any particles/ residue or any traces.	
19.	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.	
20.	Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.	
21.	Clean the utility cables limit switches and control panel with a dry lint free duster.	
22.	Reassemble the view glasses of product container of bowl and bag chamber.	
23.	Fix the duly cleaned finger bag on the finger bag holder ring and position the finger bag.	
24.	Assemble the FBD and operate the FBD as per the SOP at an inlet temperature of 70-80°C for 30 to 40 minutes to dry the sieve and finger bag.	
25.	Remove the finger bag and transfer it to the granulation spare area.	
26.	Rinse the bag chamber, explosion chamber and view glasses with 40-50 liters of purified water.	
27.	Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.	
28.	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.

