



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1. To lay down a procedure for Cleaning and Operation of Fluid Bed Dryer (GM 250 S).

2.0 SCOPE:

2.1. This procedure is applicable to Cleaning and Operation of Fluid Bed Dryer (GM 250 S).

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 log sheet”).
 - 5.1.3. Touch on manual mode. Manual mode screen shall open.
 - 5.1.4. Touch on extra shaking.
 - 5.1.5. Shake the finger bag in manually mode to dedust
 - 5.1.6. Remove the ruminants of the previous batch from the equipment and the area with vacuum cleaner as per SOP (cleaning and operation of vacuum cleaner)
 - 5.1.7. Allow sucking the powder attached with the wall and return raiser using vacuum cleaner.
 - 5.1.8. Clean the plenum, bag chamber, inlet and outlet air ducts from outside using a dry clean lint free duster.
 - 5.1.9. Clean the product container bowl with dry lint free cloth to remove any leftover material.
 - 5.1.10. Affix dully filled status label on FBD as “CLEANED” with date and signature of Production Officer verified by QA officer.
 - 5.1.11. Record the cleaning completion time in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 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. Touch on PC S/V icon on PLC and vent the PC seal. Remove the product container bowl from PC chamber.
- 5.2.3. Vent the FBT by touch on FBT S/V.
- 5.2.4. Down the finger bag by touch on BAG LFT/LWR.
- 5.2.5. Turn OFF HMI by rotating the selector anti clock wise.
- 5.2.6. 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”.
- 5.2.7. Dismantle upper plenum, lower plenum and finger bag tube. Clean with purified water using nylon scrubber.
- 5.2.8. Scrub the lower plenum, bag chamber, explosion chamber and finger bag holder ring and view glasses with a nylon scrubber using purified water from inside and outside to remove any adhered material.
- 5.2.9. Use the ladder to clean the outer surface of FBD.
- 5.2.10. Place the Dutch mesh stand below product bowl. Open the clamp and hold the Dutch mesh with base plate on stand.
- 5.2.11. Clean the Dutch mesh and base plate with purified water using nylon scrubber. Scrub the product container trolley with a nylon scrubber using purified water.
- 5.2.12. Rinse all the above parts with 130-150 liters of purified water.
- 5.2.13. 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).
- 5.2.14. Remove the Dutch weave sieve and the supporting plate.
- 5.2.15. Place the sieve in a horizontal position. Scrub the sieve with a nylon scrubber using 30-40 liters of purified water.
- 5.2.16. Scrub the supporting plate with a nylon scrubber using 10 liters purified water.
- 5.2.17. Rinse the product container bowl, sieve and supporting plate with 40-50 liters of Purified water.
- 5.2.18. Reassemble the sieve and the supporting plate.
- 5.2.19. 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.
- 5.2.20. 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.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 5.2.21. 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.
- 5.2.22. Clean the outer surface of FBD; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.
- 5.2.23. Clean the utility cables limit switches and control panel with a dry lint free duster.
- 5.2.24. Reassemble the view glasses of product container of bowl and bag chamber.
- 5.2.25. Put the cleaned FBD finger bag, pneumatic filter bag and RMG filter bag in FBD bowl.
- 5.2.26. Fit the view glasses lower and upper plenum gasket finger bag tube.
- 5.2.27. Turn ON HMI by rotating selector clock wise. Touch on main menu, main menu screen shall open. Touch on bag LFT/LWR, bag holding ring with finger bag tube LIFT and seal the ring by touch on BAG S/V.
- 5.2.28. Fit the FBD bowl containing cleaned finger bag RMG bag and pneumatic conveyor bag in product chamber, lock the clamp.
- 5.2.29. Seal the container by touch on PC S/V.
- 5.2.30. Set inlet temperature 65°C and start the machine and run 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.
- 5.2.31. Rinse the FBD bowl, bag chamber, explosion chamber and view glasses with 40-50 liters of purified water.
- 5.2.32. Wipe out the body of FBD, bag chamber, explosion chamber, trolley and bowl with a clean dry lint free duster.
- 5.2.33. Wipe all the above parts with 70% v/v IPA solution.
- 5.2.34. Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.35. Record the cleaning completion time in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).
- 5.2.36. Record the cleaning activity in Annexure-II. Cleaning Checklist of FBD (GM250S).

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 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)



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.3.3. Cleaning is applicable in case of at the end of working day, de dusting of machine with vacuum cleaner or dry by lint free cloth.

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 then type B cleaning shall be performed before use.

5.4. OPERATION:

5.4.1. Machine setting:

5.4.1.1. Ensure 'CLEANED' label duly filled and signed is affixed on the equipment.

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

5.4.1.3. Open the guard of control panel. ON the HMI by rotating HMI ON selector clock wise.

5.4.1.4. Ensure the Compressed air pressure should be NLT 5 kg/cm².

5.4.1.5. Touch 'MAIN MENU' on HMI. Main menu screen will appear. Touch 'Login' on HMI. Keypad will appear. Enter correct password by pressing the alphanumeric keys then touch 'ENTER' for confirmation.

5.4.1.6. Touch 'MANUAL' on MMI. Manual mode main screen shall appear and shows PC S/V, FBT S/V, and BAG LFT/LWR.

5.4.1.7. Touch 'BAG LFT/LWR' on HMI. Bag holding ring shall come down. Rope of finger bag holding ring integrity (any damage) should be checked before start of operation and after completion of operation.

5.4.1.8. Fit each finger one by one on the respective hook on the finger bag hanger.

5.4.1.9. Touch 'BAG LFT/LWR' on MMI. Bag holding ring start lifting up. Manually guide the guide rollers into the track.

5.4.1.10. Touch 'FBT S/V' on MMI. Pressure reading on the FBT pressure gauge shall increase to 2.0 to 3.0 kg/cm². FBD by default stopped during process, if FBT pressure is high / low then the set value
Note: Don't intervene the set value of FBT pressure in between operation.

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 S/V' on HMI. Pressure reading on the PC pressure gauge shall increase to 2.0 to 3.0 kg/cm².

5.4.2. Recipe Edit / Load / Delete:

5.4.2.1. Recipe can re-edit / loaded / deleted only in auto mode.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 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: Equipment ID number, Product recipe no, Operator Code, Batch No.
- 5.4.2.4. Load Product, Product recipe no, Operator Code, Batch No, as per respective BMR.
- 5.4.2.5. Touch 'EDIT 1' on HMI. 'RECIPE EDIT-1' screen will open with following menu: 'Process Time, Air Dry Time, Shaking Interval, Shaking Duration, Cooling Time, End Shaking Time, Dew point temperature, Print interval, DP across F. bag Inlet temperature.
- 5.4.2.6. Load Process Time, Air Dry Time, Shaking Interval, Shaking Duration, Cooling Time, End Shaking Time, Dew point temperature, Print interval, DP across F. bag, Inlet temperature as per respective BMR. Touch on RECIPE LODE on HMI.
- 5.4.2.7. Touch 'STORE' on MMI. Replace existing and save as new will show on screen.
- 5.4.2.8. Select replace existing for same product with different batch no. Recipe will get loaded in the PLC memory under given name or code.
- 5.4.2.9. Select save as new for new product and batch no. Keypad will open. Give suitable name or code for recipe. Recipe will be get loaded in the PLC memory under given name or code.
- 5.4.2.10. Touch 'MAIN SCREEN' on MMI. Recipe main screen will open.
- 5.4.2.11. To load already exist recipe Touch 'LOAD' on MMI. Stored recipe list will open. Select the recipe by touch. Warning will show as YES and NO. Touch 'YES' to load the selected recipe.
- 5.4.2.12. To delete already exist recipe touch 'DELETE' on MMI. Stored recipe list will open. Select the recipe by touch. Warning will show as YES and NO. Touch 'YES' to DELETE the selected recipe.

5.5. **Manual Mode Operation:**

- 5.5.1. Ensure main switch of control panel is ON.
- 5.5.2. After completion of machine setting touch 'MAIN MENU' on screen. Main screen will open.
- 5.5.3. Touch 'Login' and enter the correct password.
- 5.5.4. Touch 'MANUAL' on MMI. Manual screen will open.
- 5.5.5. Set the parameter displayed on screen such as process time, inlet temperature, outlet temperature, BED temperature, Dew point temperature, Relative humidity, VFD output, FCD opening, BPD opening, DP. Across Finger bag.
- 5.5.6. Touch 'PROCESS STOP' on MMI. Blower will start.
- 5.5.7. Current status of the process time, inlet temperature, outlet temperature, BED temperature, Dew point temperature, Relative humidity, VFD output, FCD opening, BPD opening, DP. Across Finger bag. Displayed on this screen.
- 5.5.8. Touch 'PREV' to open previous screen.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.5.9. At the end of operation touch 'process start to stop machine.' on MMI. Blower will stop.
- 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 'ON' position.
- 5.6.2. Touch 'Login' and enter the correct 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 AUTO MODE OFF, AUTO MODE ON will show on top screen.
- 5.6.5. Touch 'Start' to start the process on MMI.
- 5.6.6. Touch 'IND' on MMI. Next screen will open and it displays current process status for example 'set and actual value of process time' FCD output, VFD output, DP across finger bag, dew point temperature, and actual values for Inlet, outlet and product bed temperature, relative humidity, BPD output will also displayed on screen.
- 5.6.7. Process will run as per set parameters and stops automatically on completion of cycle.

5.7. Product Unloading:

- 5.7.1. Touch 'MAIN MENU' on screen. Main menu screen will appear.
- 5.7.2. Touch Login and enter the correct password.
- 5.7.3. Touch manual mode, manual mode screen shall open.
- 5.7.4. Touch 'PC S/V' on MMI. Pressure reading on the PC pressure gauge shall decrease to 0 kg/cm².
- 5.7.5. Remove out the product bed temperature sensor.
- 5.7.6. Open the Clamps and remove out the product container.
- 5.7.7. Unload the material using vacuum conveying system as per SOP (Cleaning and operation of pneumatic conveying system)
- 5.7.8. Mill the dried material using supper mill as per SOP (Cleaning and operation of super mill)
- 5.7.9. Touch 'FBT S/V' on MMI. Bag ring will vent.
- 5.7.10. Touch 'BAG LFT/LWR' bag will come down.
- 5.7.11. Remove individual finger of finger bag from the hooks of finger bag hanger.
- 5.7.12. Remove the compressed air supply pipes from FBT supporting ring.
- 5.7.13. Loose the rope around FBT supporting ring and take out the finger bag.
- 5.7.14. Turn main switch to 'OFF' position. MMI will turn OFF and reading on main air pressure will reduce to 0 bars and close the guard panel.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.7.15. 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").

5.8. SFM (Solid Flow Monitor) Challenge Test:

5.8.1. Replace the 'CLEANED' label and affix 'UNDER PROCESS' label duly filled and signed. (In Case of cleaned equipment). Or it can perform during "Type-B" cleaning.

5.8.2. Challenge test should perform without finger bag.

5.8.3. Take 200 grams of starch and put it in the FBD bowl.

5.8.4. Start the FBD in Auto Mode with 20% exhaust flap open.

5.8.5. The FBD should be tripped as the starch comes in contact with SFM.

5.8.6. After clean/reset of SFM the machine can be start.

5.8.7. 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.

5.8.8. Again take 200 grams of starch and put it in the FBD bowl.

5.8.9. Start the FBD in Manual Mode with 20% exhaust flap open.

5.8.10. The FBD should be tripped as the starch comes in contact with SFM.

5.8.11. After clean/reset of SFM the machine can be start.

5.8.12. 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.

5.8.13. 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")

5.8.14. 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 incorporated to record the cleaning of SFM sensor end of every week.

6.0 ABBREVIATION (S):

- | | | | |
|------|-----|---|-----------------------|
| 6.1. | FBD | : | Fluidized Bed Drier |
| 6.2. | IPA | : | Is-Propyl Alcohol |
| 6.3. | V/V | : | Volume/Volume |
| 6.4. | LWR | : | Lower |
| 6.5. | MMI | : | Man Machine Interface |
| 6.6. | PC | : | Product Container |
| 6.7. | DP | : | Differential Pressure |
| 6.8. | FBT | : | Finger Bag Tube |



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 6.9. FC : Flow Control
6.10. SLS : Sodium Lauryl Sulphate
6.11. SFM : Solid flow monitor

7.0 REFERENCE (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 (GM250S)		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 Department (1), Quality Assurance (1), Utility (1)
9.3. **Reference Copy (S)** : Production Department (1)

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	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

ANNEXURE II CLEANING CHECKLIST OF FBD. (GM250S)

Name of the Equipment		FLUIDIZED BED DRYER	
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 remnants 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 as per SOP.		
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.	Use the ladder to clean the outer surface bag chamber.		
9.	Rinse all the above parts with 130-150 liters of purified water.		
10.	Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz.		
11.	Scrub the supporting plate with a nylon scrubber using 10 liters 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.		
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. pellet. Reassemble the sieve and the supporting plate.		
17.	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.		
18.	Clean the Inlet Duct and Outlet Duct prior to dampers with high pressure jet cleaner and		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Fluidized Bed Dryer (Make: Alliance)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

S.No.	Activity	Activity performed
	cleanliness shall be ensured up to maximum accessible area.	
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.	

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

