



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Fluid Bed Dryer	<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 (FLUIDAIRE-250).

### 2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Fluid Bed Dryer (FLUIDAIRE-250) 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 remainants of the previous batch from the equipment and the area with 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 leftover material.



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- 5.1.8 Affix dully filled status label on FBD as “CLEANED” with signature and date 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 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.
- 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.



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- 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 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 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:



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### 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 'ON' position. Main screen will appear on PLC. Press 'LOGIN' on PLC, enter the password by pressing the numbers on the PLC, then press. '<math>\leftarrow</math>' on the PLC, then press 'MANUAL MAOD'. The screen shows-

TIME: 1 min.			
MANUAL START	MANUAL ACTION	MANUAL STOP	TIME RESET

5.4.1.3 Press the 'MANUAL START' and message displayed "MACHINE IN MANUAL MODE!!"

5.4.1.4 Then press the 'MANUAL ACTION', the screen will shows as follows,

BOWL INFLATABLE TUBES SEALED					
BAG INFLATABLE TUBES SEALED					
FINGER BAG UP			BAG SHAKING OFF		
EXHAUST DAMPER CLOSE			EARTHING ON		
BLOWER ON/OFF	BOWL SEAL	BAG SHAKING	BAG UP/DN	BAG SEAL	NEXT

5.4.1.5 Press the 'BAG UP/DN' on PLC. Pneumatic cylinder will come down.

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

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

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. Touch bag seal on MMI. Pressure gauge shall increase to 2.0 – 2.5 Kg/cm<sup>2</sup>. FBD by default stopped during process, if FBT pressure is high / low against the set value.

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

5.4.1.10 Press the 'BAG UP/DN' on PLC. Pneumatic cylinder will start lifting up. Manually guide the track.



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5.4.1.11 Place the FBD bowl containing material to be dried in between the lower plenum and retarding chamber and lock by hook at the front. Insert the product bed temperature sensor in the temperature sensor port of product container.

5.4.1.12 Press the 'BAG SEAL' on PLC. Finger bag sealed.

5.4.1.13 Press the 'BOWL SEAL' on PLC. Bowl sealed, press 'BOWL SEAL' again to unseal.

### 5.4.2 Recipe Edit / Load / Delete:

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

5.4.2.2 Press 'HOME' to go to the 'HOME SCREEN', then press the 'MANUAL MODE' and then press 'MANUAL STOP' to exit from the manual mode.

5.4.2.3 Press 'RECIPE EDIT' on PLC. Recipe main screen will appear as-

DATA ENTRY					
03/11/10		11:51:05			
LOGIN	LOAD RECIPE	SAVE RECIPE	APPEND RECIPE	AUTO SELECT	DELETE RECIPE

5.4.2.4 Press 'LOGIN' and enter the respective password. Load the required recipe by pressing the '▲', '▶', '▼' and '◀' on the PLC. Enter "Program No.:", "Product Code.:", "Batch No.:", "Lot No.:", "Operator Code.:", "Process Time.:", "Air Dry Time: min, Shaking Interval: min, Shaking On Time: sec, Cooling Time: min, End Shaking: sec, Periodic Print: sec, Inlet Temp Set Point.:", "Damper Position: % open, Outlet Temp Set Point.:", "Product Temp Set Point: and Face Bypass Damper.:"

5.4.2.5 Load the above all parameters as per respective BMR.

5.4.2.6 Save the loaded recipe by pressing the 'Save Recipe' it shows:

<u>Save Recipe</u>
Replace existing
Enter = Select, PREV = Cancel



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5.4.2.7 If you want to replace the existing recipe, then press 'Enter', and if you want to save as another one, then press the '▼'. The 'Replace existing, converted to 'Save as new', then press '<␣'. Screen shows:

Save recipe as:

Name:

OK	CANCEL
----	--------

5.4.2.8 Enter name by press on PLC, then select 'Ok' by press '<␣' and to save press '<␣' again. Message shows 'Recipe saved'.

5.4.2.9 Press 'Load Recipe' it shows

1
Enter = Select, PREV = Cancel

5.4.2.10 Press 'Enter' message display

WARNING
Load recipe "1"?
YES NO

Press 'YES' recipe loaded.

5.4.2.11 To delete already exist recipe by pressing the 'Delete Recipe', screen shows:

ALL FILES
1
MAC
Enter = Select, PREV = Cancel

5.4.2.12 Select the respective recipe, press '<␣', screen shows warning message:

WARNING
Delete recipe "MAC"?
YES NO

Press 'YES', and '<␣' recipe deleted.

### 5.5 Manual Mode Operation:

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

5.5.2 Press the 'LOGIN' and enter the password.



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5.5.3 After completion of machine setting press the 'MANUAL MODE' on screen. Manual mode main screen will open. It shows 'MANUAL START', 'MANUAL ACTION', 'MANUAL STOP', and 'TIME RESET' at the bottom of the screen.

5.5.4 Press the 'MANUAL START' and message displayed "MACHINE IN MANUAL MODE!!"

5.5.5 Then press the 'MANUAL ACTION', the screen will shows as follows,

BOWL INFLATABLE TUBES SEALED					
BAG INFLATABLE TUBES SEALED					
FINGER BAG UP			BAG SHAKING OFF		
EXHAUST DAMPER CLOSE			EARTHING ON		
BLOWER ON/OFF	BOWL SEAL	BAG SHAKING	BAG UP/DN	BAG SEAL	NEXT

5.5.6 Then press the 'BAG SEAL' and check the bag is sealed properly.

5.5.7 Press the 'BOWL SEAL'. Bowl sealed.

5.5.8 Press the 'BLOWER ON/OFF', the blower will start. Press the 'NEXT' the screen will shown as follows,

	SET	ACTUAL
PID VALVE		100 %
FACE BYPASS	0%	48%
PREV	FACE DAMPER	PRINT

5.5.9 At the end of operation touch 'BLOWER' on MMI. Blower will stop. Touch 'MAN' on MMI. Manual mode main screen will open. 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 FBD run in AUTO MODE from the Recipe screen and also from Main screen.

5.6.2 From 'RECIPE MAIN SCREEN' select the 'AUTO SELECT'. Screen shown as:

AUTO ENABLE	AUTO ACTION	AUTO DISABLE

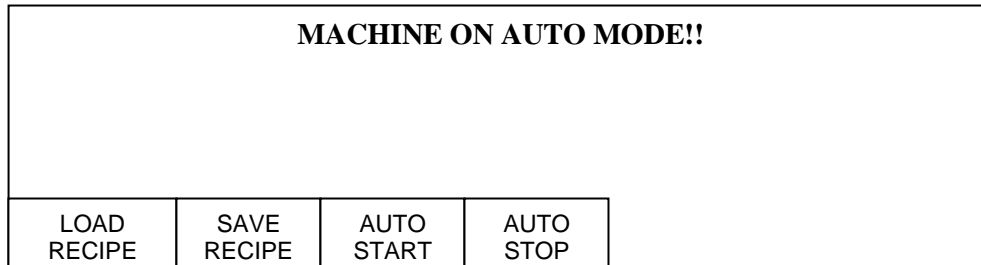
5.6.3 Press 'AUTO ENABLE' the FBD is now in 'AUTO MODE', message shown on the screen 'MACHINE ON AUTO MODE!!'



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5.6.4 Press 'AUTO ACTION' screen shown as:



5.6.5 From this screen also save and load the respective recipe. To start the operation press 'AUTO START' and to stop the operation press the 'AUTO STOP'

5.6.6 After press the 'AUTO START', process will run as per set parameters and stops automatically on completion of cycle.

5.6.7 After completion of AUTO CYCLE go to the home screen.

**5.7 Product Unloading**

5.7.1 Open Manual mode main screen.

5.7.2 In the 'MANUAL MODE' screen firstly press the 'BAG SHAKING' then press 'BOWL SEAL', to unseal the bowl.

5.7.3 Remove out the product bed temperature sensor.

5.7.4 Open the front Clamps and remove out the product container.

5.7.5 Then press 'BAG SEAL' to unseal the bag and then press the 'BAG UP/DN', pneumatic cylinder will come down.

5.7.6 Remove individual finger of finger bag from the hooks of finger bag hanger.

5.7.7 Remove the compressed air supply pipes from FBT supporting ring.

5.7.8 Uptight the rope around FBT supporting ring and take out the finger bag.

5.7.9 Turn main switch to 'OFF' position. PLC will turn OFF and press the EMERGENCY SWITCH.

5.7.10 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 '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.





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- 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.
- 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 PLC : Programmable Logical Control
- 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 SFM : Solid Flow Monitor



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### 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

### 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 (FLUIDAIRE-250)		Logbook
Annexure-III	SFM sensor weekly cleaning record		Logbook

### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (s)** : Production Department (1), Quality Assurance (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	NA





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### ANNEXURE II CLEANING CHECKLIST OF FBD (FLUIDAIRE-250)

<b>Name of the Equipment</b>	<b>Fluidized Bed Dryer (FLUIDAIRE-250)</b>		
<b>Equipment I.D. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

S.No.	Activity	Activity performed
1.	Remove "UNDER PROCESS" label and affix dully-filled "UNDER CLEANING" label to the machine.	
2.	Shake the finger bag in manually mode to dedust.	
3.	Remove the remainants of the previous batch from the equipment and the area with vacuum cleaner.	
4.	Bring down the finger bag by operating the finger bag holding ring 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. pellet. Reassemble the sieve and the supporting plate.	
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 10-20 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 FBD filter bag in FBD bowl.	
22.	Assemble the FBD and operate the FBD at an inlet temperature of 65°C until the outlet 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 40-50 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.	

**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.

