



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Fluidized Bed Dryer 60 kg (Bectochem)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning of Fluidized Bed Dryer 60Kg (Bectochem).

2.0 SCOPE :

This procedure is applicable to Cleaning of Fluidized Bed Dryer 60Kg (Bectochem) located in granulation area.

3.0 RESPONSIBILITY:

Production: Technical Associate/ Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 TYPE A:

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.

4.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine with date and signature of production officer.

4.1.2 Enter the cleaning start time in equipment sequential log book as per SOP.

4.1.3 Shake the finger bag in manual mode to de-dust.

4.1.4 Remove the traces of residue of the previous batch from the equipment and the area with dry lint free cloth.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Fluidized Bed Dryer 60 kg (Bectochem)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.1.5 Clean the lower plenum, bag chamber, inlet and outlet air ducts and retarding chamber from outside using a dry clean lint free cloth.
- 4.1.6 Clean the product container bowl with dry lint free cloth to remove any leftover material.
- 4.1.7 Dismantle the sampling port and clean it with dry lint free cloth.
- 4.1.8 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the production officer.
- 4.1.9 Record the cleaning completion time in equipment sequential log book as per SOP.

4.2 TYPE B:

This is a cleaning procedure for Changeover of product with different actives / color / descending potency or after maintenance of contact parts.

- 4.2.1 Follow the procedure from step 4.1.1 to 4.1.4.
- 4.2.2 Cover the MMI, light fixture and all other electrical parts with polyethylene bags
- 4.2.3 Pull out the product container bowl; dismantle the view glass of product container bowl and retarding chamber.
- 4.2.4 Bring down the finger bag by operating the touch screen.
- 4.2.5 Remove the bag from the finger bag holding ring and clean the finger bag as per SOP.
- 4.2.6 Apply approx.70.0 to 80.0 kg purified water to clean the bag chamber, lower plenum, retarding chamber and finger bag holder ring.
- 4.2.7 Scrub above parts by using nylon scrubber.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Fluidized Bed Dryer 60 kg (Bectochem)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.2.8 Wash above parts using approx. 50.0 to 60.0 kg purified water from inside and outside to remove the adhered material.
- 4.2.9 Rinse all the above parts with approx.30.0 to 40.0 kg purified water.
- 4.2.10 Remove the Dutch mesh and the supporting plate from bowl.
- 4.2.11 Apply approx.20.0 to 30.0 kg purified water to clean the product container bowl and trolley.
- 4.2.12 Scrub it with nylon scrubber and wash with approx.20.0 to 30.0 kg purified water.
- 4.2.13 Rinse it by applying approx.20.0 to 30.0 kg purified water.
- 4.2.14 Place the Dutch mesh and supporting plate in a horizontal position.
- 4.2.15 Apply approx. 20.0 to 30.0 kg purified water to remove the adhered material.
- 4.2.16 Scrub the Dutch mesh & supporting plate with a nylon scrubber and wash the Dutch mesh & supporting plate by using approx. 20.0 to 30.0 kg purified water.
- 4.2.17 Rinse the Dutch mesh by applying approx. 30.0 to 40.0 kg purified water.
- 4.2.18 Place the Dutch mesh and the supporting plate on a clean SS table. Assemble the Dutch mesh and the supporting plate with the FBD bowl.
- 4.2.19 Scrub the supporting arms, inlet air duct and the lifting chamber with a nylon scrubber using 20.0 to 30.0 kg purified water and wash supporting arms, inlet air duct and lifting chamber with 30.0 to 40.0 kg purified water.
- 4.2.20 Clean the utility cables limit switches and control panel with a clean dry lint free cloth.
- 4.2.21 Clean the view glasses of by using 4.0 to 6.0 kg purified water. Rinse it with 4.0 to 6.0 kg purified water.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.2.22 Reassemble the view glasses of product container of bowl and retarding Chamber.
- 4.2.23 Fix the duly cleaned finger bag on the finger bag holding ring and position the finger bag.
- 4.2.24 Assemble the FBD and operate at an inlet temperature of 80-90°C for drying the Dutch mesh and finger bag. After complete drying store the FBD bag by covering with a polythene bag and label as 'CLEANED' status label with date and signature of the production officer.
- 4.2.25 Remove the polyethylene bags from MMI, light fixture and electrical parts and wipe out the body of FBD, bag chamber, retarding chamber, lower plenum, trolley and bowl, motor cover, MMI with clean lint free cloth soaked in purified water.
- 4.2.26 Wipe all the above parts with wet lint free cloth soaked in 70% v/v IPA solution.
- 4.2.27 Replace "UNDER CLEANING" and affix the status "CLEANED" label on FBD with date and signature of the production officer.
- 4.2.28 Record the cleaning completion time in equipment sequential log book as per SOP.

5.0 ANNEXURE (S):

Annexure-I: Cleaning checklist of FBD 60 kg (Bectochem).

6.0 REFERENCE (S) :

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Procedure for area line clearance.

SOP: Procedure for Inventory, cleaning and storage of FBD finger bag.

7.0 ABBREVIATION (S) /DEFINITION (S) :



PHARMA DEVILS

PRODUCTION DEPARTMENT

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Title: Cleaning of Fluidized Bed Dryer 60 kg (Bectochem)	Effective Date:
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Issue Date:	Page No.:

BMR : Batch Manufacturing Record

FBD : Fluidized Bed Dryer

PLC : Programmable Logic Controller.

RMG : Rapid Mixer Granulator

SOP : Standard Operating Procedure.

HEPA: High efficiency particulate air

IPA : Isopropyl Alcohol

S.S. : Stainless Steel.

V/V : Volume / Volume

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---