PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Fluid Bed Processor	**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 Processor (APCG-450).

2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Fluid Bed Processor (APCG-450) 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 lot to next lot 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 equipment usage and cleaning log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.3 Ensure that the main power supply is switched OFF.

5.1.4 Shake the finger bag/ bonnet filter or retention screen in manually mode to dedust. (If applicable)

5.1.5 Disconnect the Atomization and needle air pipes from the spraying guns and clean with a dry lint free duster.

5.1.6 Disconnect the Product Bed Temperature (PBT) sensor & unseal the container, then remove the product bowl, swing out the expansion chamber and clean with a dry clean lint free duster to remove any leftover material.

5.1.7 Unseal the finger bag/bonnet filter or retention screen by pressing on LH -UNSEAL, and RH-UNSEAL on screen.

5.1.8 Down the finger bag/bonnet or retention screen filter by pressing on LH -DOWN and RH-DOWN on screen.

5.1.9 Clean the inside and outside of the retention screens with a dry lint free duster followed by compressed air.

5.1.10 Remove the remnants of the previous batch from the equipment and the area with a dry clean lint free duster.

5.1.11 Clean the powder attached with the wall and return raiser with a dry clean lint free duster.

5.1.12 Dismantle the air channelizer to the product bowl by unclamped the toggle clamps.

5.1.13 Remove the UP-bed and down bedplate, fine mesh and clean with a dry lint free duster.

5.1.14 Dismantle the spraying system and clean with a dry lint free duster.

5.1.15 **Method of cleaning of Spray system and corresponding tubes:**

5.1.15.1 Clean the solution feeding vessel with 10-20 liters of purified water.

5.1.15.2 Take 50-60 liters of purified water in vessel.

5.1.15.3 Removes the product inlet and outlet tubes from the nozzles of the solution-feeding vessel.

5.1.15.4 Dip the tubes into purified water.

5.1.15.5 Reduce the atomizing air pressure to zero.

5.1.15.6 Run the peristaltic pump at high speed.

5.1.15.7 Continue this till fresh water comes out from the spray guns.

5.1.15.8 Dismantle the spray gun and clean with a dry lint free duster and dry the corresponding tubes with compressed air.

5.1.15.9 Unscrew the four hex bolts and then remove the spraying assembly from the FBP.

5.1.15.10 Flush the tubes with 50 liters of purified water.

5.1.15.11 Remove the nozzle from the spray gun.

5.1.15.12 Clean the utility cables limit switches and control panel with a dry lint free duster.

5.1.15.13 Affix dully filled status label on FBP as “CLEANED” with date and signature of Production Officer verified by QA officer.

5.1.15.14 Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.15.15 **NOTE:** Ensure that spray guns & corresponding tubes cleaned and there is no deposition of coating solution or solid materials either in tube or in the nozzles of spray guns.

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 Remove "EQUIPMENT STATUS" label and affix dully-filled "UNDER CLEANING" label to the machine.

5.2.2 Enter the cleaning start time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.3 Shake the finger bag in manually mode to dedust. (If applicable)

5.2.4 Remove the remnants of the previous batch from the equipment and the area with a dry clean lint free duster.

5.2.5 Clean the powder attached with the wall and return raiser with a dry clean lint free duster.

5.2.6 Disconnect the Atomization and needle air pipes from the spraying guns and clean with a dry lint free duster.

5.2.7 Disconnect the Product Bed Temperature (PBT) sensor & unseal the container, then remove the product bowl, swing out the expansion chamber and clean with a dry clean lint free duster to remove any leftover material.

5.2.8 Unseal and bring down both right and left finger bag/ bonnet filter or retention screen by operating the finger bag/ bonnet filter or retention screen holding ring towards lower side by click on finger bag LH DOWN and RH DOWN on PLC.

5.2.9 Follow the cleaning procedure of 5.1.9 to 5.1.14.

5.2.10 Remove the finger bag rings from the finger holding coupling and clean the bags as per SOP (Cleaning and utilization of FBD finger bag and RMG filter bag).

5.2.11 Dismantle the air channelizer to the product bowl by unclamped the toggle clamps.

5.2.12 Remove the UP-bed and down bedplate, fine mesh.

5.2.13 Dismantle the spraying system.

5.2.14 Remove the product bowl, and swing out the expansion chamber.

5.2.15 Scrub the supporting plate with a nylon scrubber using purified water.

5.2.16 Remove the inner partition, fine sieve, perforated bottom, sampling port & cup.

5.2.17 Rinse the Wurster container, inner partition with fixing components; fine sieve, perforated bottom, sampling port & cup with 60-80 liters of Purified water.

5.2.17.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.12 with 60-80 liters 0.4 % NAOH solution and followed by with 60-80 liters purified water.

5.2.18 Bring down the both two-finger bag or retention screens or bonnet filter by operating the finger bag holding ring towards lower side.

5.2.19 Remove the finger bag rings from the finger holding coupling and clean the bags.

5.2.20 Pull out the expansion chamber; dismantle the elliptical shaped observation window (1 nos.) of expansion chamber, elliptical shaped observation window (01 nos.) of product container bowl (top spray bowl & bottom spray bowl each) and viewing glass (2 nos.) of bag chamber.

5.2.21 Scrub the expansion chamber and finger bag holder ring and view glasses with gasket, inflated gasket (5 nos.), and inflated tube ring with a nylon scrubber using purified water from inside and outside to remove any adhered material.

5.2.21.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.16 with 0.4 % NAOH solution and followed by with purified water.

5.2.22 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.

5.2.23 Use the ladder to clean the outer surface bag chamber and expansion chamber.

5.2.24 Rinse all the above parts with 60-70 liters of purified water.

5.2.24.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.18 with 60-70 liters 0.4 % NAOH solution and followed by with 60-70 liters purified water.

5.2.25 Scrub the product container bowl and trolley with a nylon scrubber using purified water.

5.2.25.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.19 with 0.4 % NAOH solution and followed by with purified water.

5.2.26 Scrub the sieve and supporting plate with nylon scrubber using 40-50 liters of purified water.

5.2.26.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.20 with 40-50 liters 0.4 % NAOH solution and followed by with 40-50 liters purified water.

5.2.27 Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate.

5.2.28 Method of cleaning of Spray system and corresponding tubes

5.2.28.1 Follow the cleaning procedure as 5.1.15.1 to 5.1.15.11.

5.2.29 Affix dully filled status label on FBP as “CLEANED” with date and signature of Production Officer verified by QA officer.

5.2.30 Method of cleaning of Retention Screens or bonnet filter/ Finger bag.

5.2.30.1 Bring down the both two-finger bag or retention screens or bonnet filter by operating the finger bag holding ring towards lower side.

5.2.30.2 Remove the finger bag rings from the finger holding coupling and clean the bags.

5.2.30.3 Rinse the retention screens with 20-25 liters of purified water.

5.2.30.4 Scrub the inside and outside of the screens with nylon scrubber using 25-30 liters of purified water.

5.2.30.4.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.23.2 with 25-30 liters 0.4 % NAOH solution and followed by with 25-30 liters purified water.

5.2.30.5 Rinse and wash the retention screens with sufficient quantity of purified water.

5.2.31 Scrub the outside of the FBP, supporting arms inlet air duct and the inlet chamber with a nylon scrubber using 40-50 liters of purified water.

5.2.31.1 **Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.24 with 40-50 liters 0.4 % NAOH solution.

5.2.32 Clean the outer surface of FBP; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.

5.2.33 Clean the utility cables limit switches and control panel with a dry lint free duster.

5.2.34 Reassemble the observation window of product container, expansion chamber and bag chamber.

5.2.35 Put the cleaned FBP finger bag in FBP bowl on top spray FBP bowl.

5.2.36 Assemble the FBP and operate the FBP 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.

5.2.37 Rinse the FBP product bowl, bag chamber, expansion chamber and view glasses with 50-60 liters of purified water.

5.2.38 Wipe out the body of FBP, bag chamber, expansion chamber, trolley and bowl with a clean dry lint free duster.

5.2.39 Wipe all the above parts with 70% v/v IPA solution.

5.2.40 Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.

5.2.41 Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.42 Record the cleaning activity in Annexure II (Cleaning Checklist of Fluidized Bed Processor (APCG-450).

5.3 Frequency

5.3.1 Type 'A' cleaning is applicable after completion of every lot/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 Validation".

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 Validation".

5.3.3 Shift end cleaning is applicable in case of at the end of working day, Dedusting of machine with dry lint free cloth.

5.3.3.1 **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. Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet) cleaning as per SOP "Cleaning Validation".

5.3.3.2 Always use dedicated product pipes.

5.3.3.3 Clean the machine with 0.4% NaOH solution if previous product coating solution contains enteric coating polymer material/Methacrylic Acid Co-Polymer. Final rinsing to be performed with purified water.

5.3.3.4 Clean the machine with 2% Sodium Lauryl Sulphate if previous product used in area is Efavirenz. Final rinsing to be performed with purified water.

5.4 OPERATION:

5.4.1 **Machine setting**

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

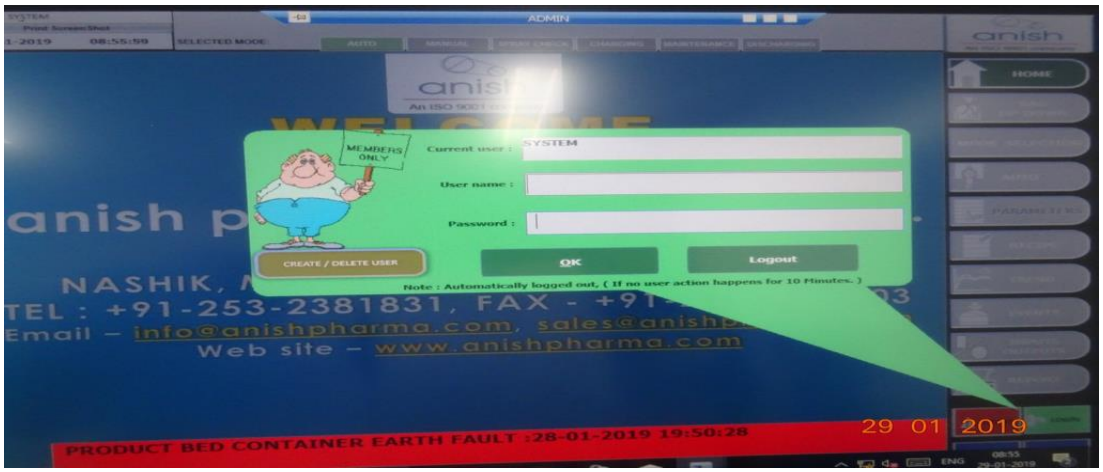
5.4.1.2 Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet). Affix 'EQUIPMENT STATUS' label duly filled and signed on the equipment.

5.4.1.3 Ensure that the compressed air and main electric supply is 'ON' from service Area. Fix all the sensors to the machine. Ensure that Humidity selector switch always should be at on position and in case of high humidity required then "PSG running" control should be on.

5.4.1.4 Set the spraying system in the air channelizer, and to the spraying system fit the needle pressure and atomization pressure PU pipes and solution-loading pipe.

5.4.1.5 Turn main switch to 'ON' position. Main screen will appear on PLC. Remote monitor screen will display, one pop up window appears for open and close, and then select open (my device). Then double click on remote desktop icon at desktop, after that remote desktop connection window appears. Then move to task bar right side and open keyboard. Then enter, login details at computer section then touch connect on next window. Here enter required user name and password and click on OK button. Welcome screen will appear as shows below-

5.4.1.6 Then click on Login and then enter individual user name and password press on ok button as shown below.

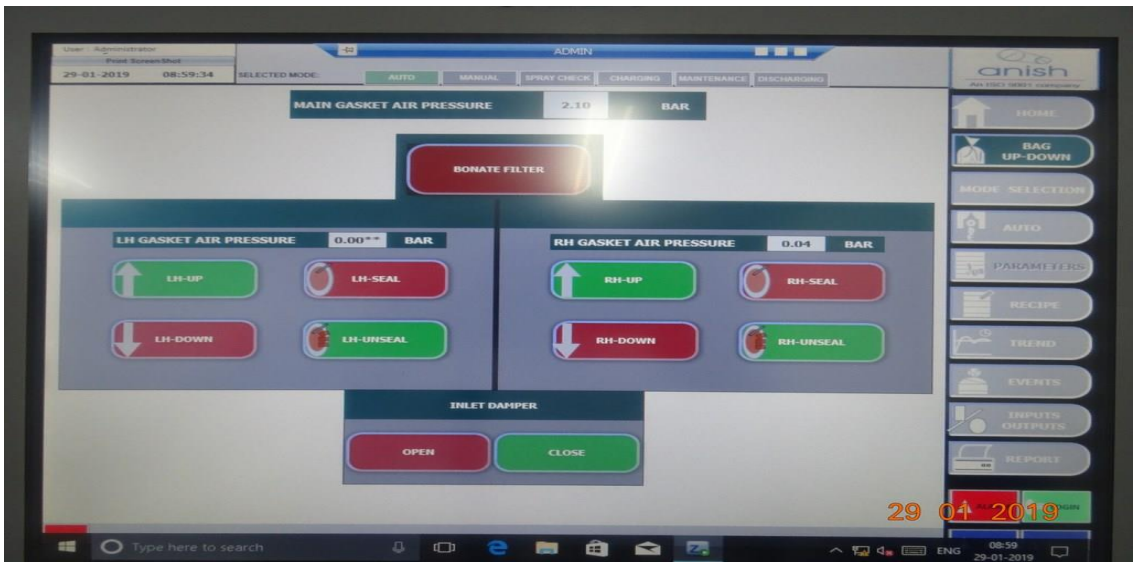


5.4.1.7 Three levels Password assigned as Level-I (for Technical Associates and Trainee Technical associate), Level-II (For Officers and Executives) and Level –III (For Shift in charge /Managers an Above).

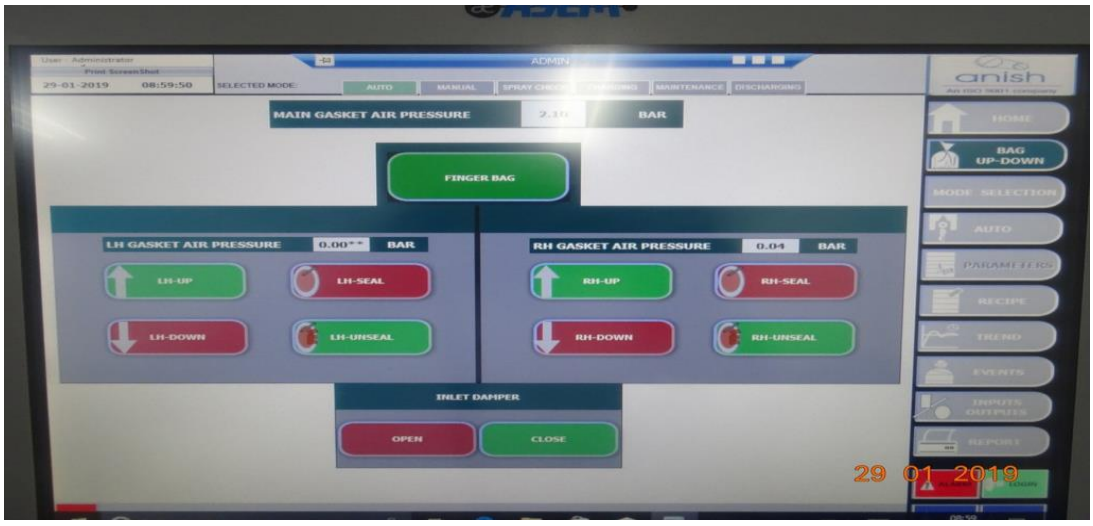
5.4.1.8 At Level-I (Technical Associates and Trainee Technical associate) can ON/OFF the machine, view all parameters and reports only, at Level-II (For Officers and Executives) they can do all of level-I plus edit the parameters, load recipe and Mode selection and at Level –III (For Shift in charge /Managers an Above), they can do all of level-I & II and further they create, delete and edit (up to 10 stages) recipe and user creation, delete and change password.

5.4.1.9 For creation of new ID click on “create/ delete user” option at Login screen.

5.4.1.10 After Login, press BAG UP-DOWN Option button on PLC. The screen shows:



5.4.1.11 Click on bonnet filter for change of mode to finger bag and for the attachment of finger bag. Select BONATE FILTER or FINGER BAG screen as per requirement. The finger bag selected screen shows:



Note: Install bonnet filter or retention or finger bag screen as per requirement in BONATE FILTER option.

5.4.1.12 After connecting both the finger bags or retention screen press RH-UP & LH-UP button to up the finger bags, pneumatic cylinder of righthand side & lefthand side will move up (set the position manually) After that to seal the bags/ or retention screen, press RH-SEAL and LH-SEAL button.

5.4.1.13 To down the finger bags or retention screen, first unseal them and then press RH-DOWN & LH-DOWN buttons, Pneumatic cylinder of righthand side and lefthand side will come down.

CAUTION:

5.4.1.13.1 Do above operations only when expansion chamber is in full open condition.

5.4.1.13.2 If finger bag/ retention screen is not in UP condition then next screen will not appear.

5.4.1.13.3 After UP the finger bag/ retention screen, it will seal manually. The sealing pressure of the gasket has to be set always NMT 3 bar.

5.4.1.14 Set the spraying system in the air channelizer.

5.4.1.15 Close the expansion chamber.

5.4.1.16 Place the FBP product bowl containing material to be processed in between the plenum and expansion chamber, and then Insert the product bed temperature sensor in the temperature sensor port of product container, fit the atomizing air pressure pipe, needle pressure pipe and solution loading pipe.

5.4.1.17 In BAG UP-DOWN screen, the screen shows inlet damper ON/OFF button.

5.4.1.18 Here OPEN or CLOSE the Inlet Damper as required.

5.4.1.19 Press MODE button to go to next screen. Here MODE selection screen will appear.

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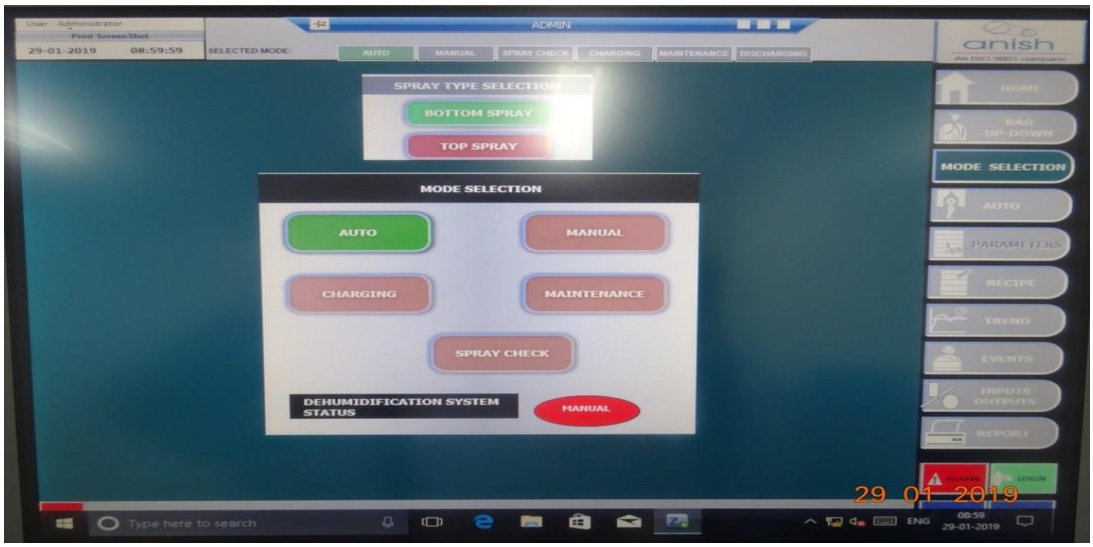

5.4.1.20 First select the type of spray required that is Bottom Spray or Top Spray. Then select the mode as required. Then run the product.

5.4.1.21 After completion of activity to DOWN the finger bag/ retention screen press RH BAG DOWN, Pneumatic cylinder of righthand side will come down, and LH BAG DOWN, Pneumatic cylinder of left hand side will come down. After that to seal bag/ retention screen press bag SEAL button, and to unseal press UNSEAL bag button.

5.4.2 **Setting of Wurster Chamber:**

5.4.2.1 Height of the wurster chamber is depending on the required fluidization in a particular product.

5.4.2.2 Height of the wurster chamber can be adjusted from 0-50 mm with the help of a handle.

5.4.2.3 For up the wurster chamber rotate the handle clockwise direction and for down the wurster chamber rotate the handle anticlockwise.

5.4.3 **Recipe Create/ Edit / Load / Delete:**

5.4.3.1 Recipe can be created/ edited / loaded / deleted in auto mode.

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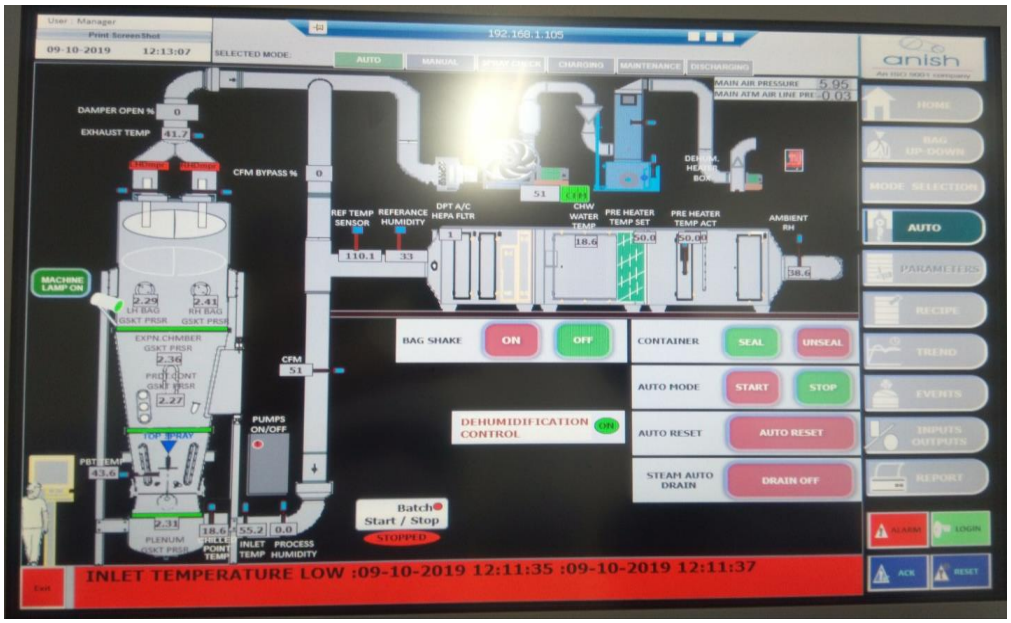
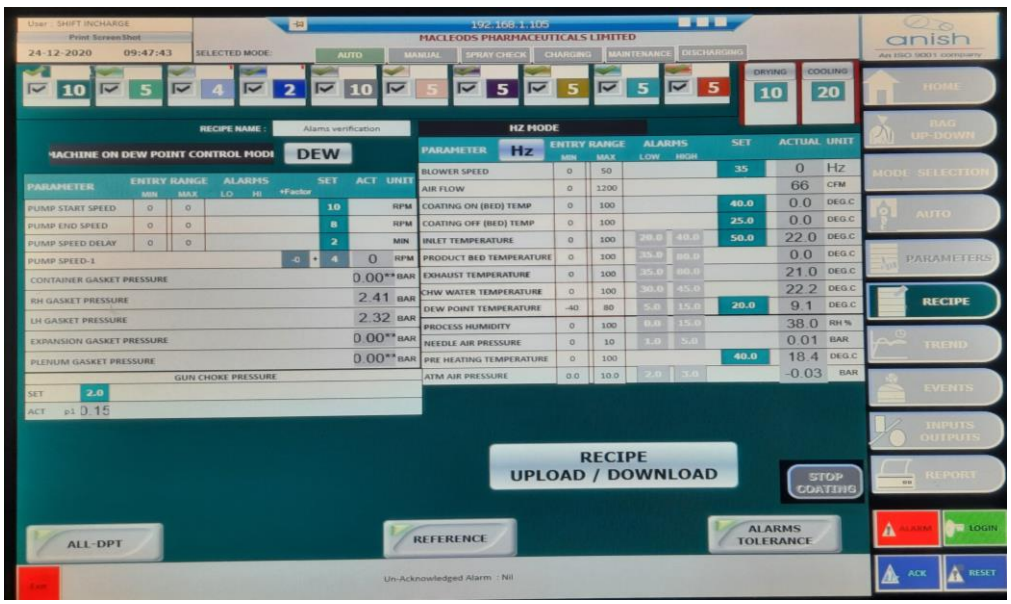
5.4.3.2 Select the AUTO MODE from Mode Selection screen.



5.4.3.3 After AUTO MODE Selection, click on Recipe button on the welcome screen. The next screen shows the set parameters screen.



5.4.3.3.1 Reference button added for the setting of Reference Temperature and Reference Humidity. When we set this the machine is starts when set temperature and humidity exceeds from reference temperature and humidity.

Reference Setting	Min	Max	Set	Actual	Unit
Reference Temperature	0	100	60	60	DEG.C
Reference Humidity	0	100	10	10	RH%
Reference Dew Point	-40	80	10	10	DEG.C

5.4.3.4 Here click on the Recipe upload/download button to create, edit, upload, delete and download recipe. In this screen there are stages for the setting of parameters. Set the parameters with minimum and maximum value in these stages, drying and cooling time set at the end of the last stage. There is “0” for absent and “1” for present option is available in stage selection setting.

5.4.3.5 For creation of new recipe click on new recipe a popup come on screen to enter product name.

5.4.3.6 Give name here for new recipe then set the parameter and save by clicking on save recipe.

5.4.3.7 After selection of recipe click on report, then select the Production report, here a screen appears on that we can put the Product name, batch no. operator name etc.

5.4.3.8 Product name and operator name by default save in report.

5.4.3.9 After selection of recipe come back to previous screen by click on back button.

5.4.3.10 Here set the gun choke pressure for the gun.

5.4.3.11 Select the Machine Control Mode CFM / HZ as per recipe requirement and then select the stages at the top of the display screen.

5.4.3.12 Select the Machine Control Mode Dew Point / RH as per recipe requirement and then select the stages at the top of the display screen.

5.4.3.13 Select the Alarm tolerance button. Here set the low and high parameters for the Alarms.

5.4.3.14 After loading all the parameters go to Selected Mode Auto on the welcome screen.

5.4.3.15 Next screen will appear with P and I diagram and CONTAINER SEAL-UNSEAL, AUTO MODE ON-OFF, AUTO RESET, STEAM AUTO DRAIN ON- OFF options.

5.4.3.16 Seal the container; click on Auto Reset button before start the Auto Mode.

5.4.3.17 Click on Steam Auto button to Drain OFF the condensate as per need, when there is fall in Inlet temperature.

5.4.4 **Procedure for checking of spray rate and Setting of speed of Peristaltic pump as per requirement of spray rate**

5.4.4.1 Checking of spray rate:

During the spraying of the coating solution, it is collected in weighed beaker, from spray gun, for one minute. The spray rate is calculated as gm/ minute.

$$\text{Spray rate (g/min)} = \frac{\text{Weight of solution sprayed in beaker (g)} \times 60}{\text{Time elapsed for spray displayed on stopwatch (sec)}}$$

Frequency: At the time of starting of batch.

5.4.4.2 Setting of speed of Peristaltic pump as per requirement of spray rate:

The spray rate is checked at 5 RPM and spray rate to be achieved is calculated based on actual spray rate received at 5 RPM

If spray rate is X g/ min and RPM is 5

To achieve the spray rate of Y g/min calculates as following:

$$\text{Speed of Peristaltic pump RPM at desired spray rate} = \frac{Y \times 5}{X}$$

Frequency: At the time of starting of batch.

5.4.4.3 Calculate the average spray rate for time period as per following formula:

$$\text{Average Spray rate} = \frac{\text{Initial weight (in Kg)} - \text{Final weight (in Kg)} \times 1000}{\text{Time period (in Minutes)} \times \text{No. of spray guns}}$$

Frequency: As per Batch Manufacturing record.

5.5 Manual Mode Operation

5.5.1 Select Manual Mode from the MODE SECLECTION screen, and then click on PARAMETERS button on the welcome screen.

5.5.2 Select the Machine Control Mode CFM / HZ as per requirement.

5.5.3 Select the Machine Control Mode Dew Point/ RH as per requirement.

5.5.4 After that select the SELECTED MODE MANUAL button on the welcome screen.

Select the Machine Control Mode Dew Point / RH as per requirement

Screen shows the following parameters, Set blower Speed, Set CFM/ AIR FLOW, Coating ON (Bed) Temperature, Coating OFF (Bed) Temperature, Set Inlet Temperature, Pre-heating Temperature, Exhaust Temperature, Product bed Temperature, CHW point Temperature, Process Humidity, Dew Point, Needle air pressure, Bag shaking delay and bag shaking strokes.

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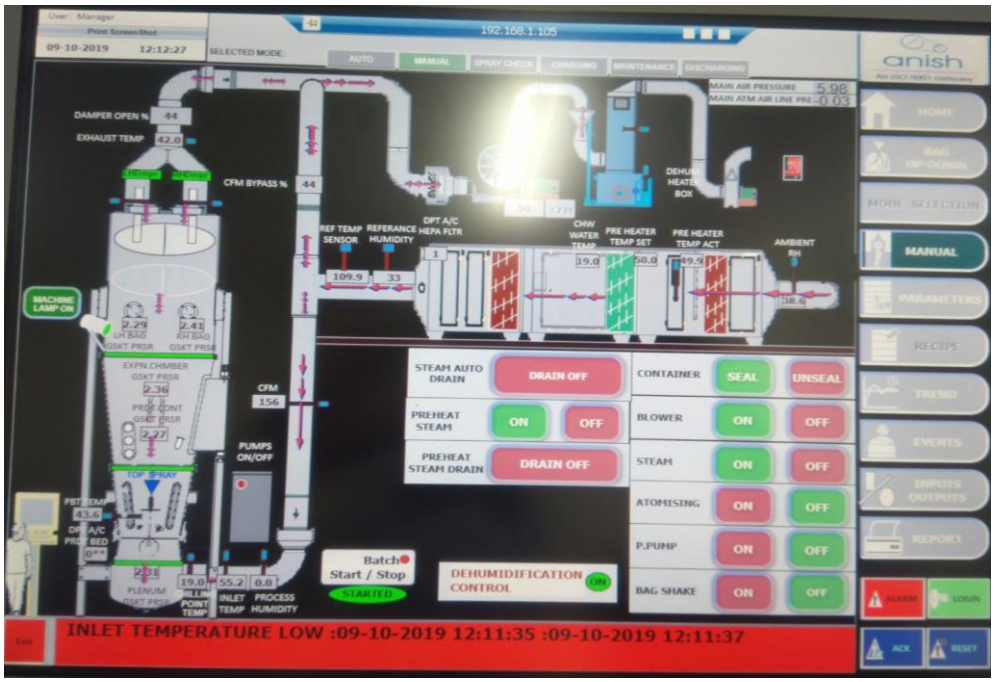
5.5.5 Next Screen will appear to set the parameters as require.



5.5.6 Screen appears with P and I diagram and CONTAINER SEAL/UNSEAL, BLOWER ON/OFF, STEAM ON/OFF, ATOMISING ON/OFF, PERISTALTIC PUMP ON/OFF, BAG SHAKE ON/OFF, STEAM AUTO for DRAIN ON- OFF options. Another screen appears here for HUMIDIFIER CONTROL ON/OFF, PRE HEATER ON/OFF and PRE HEATER DRAIN ON/OFF options

5.5.7 To start the machine in manual mode first connect PBT sensor, press SEAL to seal the Container, ON the Atomizing pressure, ON the Blower, ON the Steam, then ON the Peristaltic Pump.

5.5.8 Click on Batch Start/Stop option in the P & I Diagram screen.

5.5.9 Next screen appear to enter the Product Name, Batch Number, Operator Name, Lot Number. Click on the Batch Start/Stop button to start or stop the batch and then close it.

5.5.10 Select the MACHINE LAMP option on P & I diagram screen to ON/OFF the Machine Lamp.

5.5.11 Select the Pump ON/OFF button on P & I diagram, next screen will appear with peristaltic pumps ON/OFF options.

5.5.12 Here spray gun pressure and speed of the pumps can be set.

5.5.13 At the end of the operation first ‘OFF’ the Peristaltic Pump, ‘OFF’ the Steam, ‘OFF’ the Blower, ‘OFF’ the Atomizing pressure then bag shaking manually as required disconnect the Product Bed Temperature Sensor then ‘UNSEAL’ the Container.

5.5.14 In machine both "AUTO" and "MANUAL" mode available machine can be run as per requirement "AUTO" or "MANUAL" mode.

Caution: At the time of machine running always monitor the pressure across product bed. Normally it is 6- 7 inches of water but if it is up to 20 or above it means sieves chocked.

5.6 CHARGING MODE:

5.6.1 Select the Charging mode from the MODE SELECTION on the welcome screen.

5.6.2 After selection click on SELECTED MODE CHARGING on the welcome screen. Screen appear with following parameters:

PARAMETERS	ENTRY RANGE		SET	ACTUAL	UNIT
	MIN	MAX			
ATM AIR PRSSURE	0	10	--------	0	BAR
SET BLOWER SPEED	0	50	35	35	HZ

CONTAINER	SEAL	UNSEAL

BLOWER	ON	OFF

ATOMISING	ON	OFF

5.6.3 Charging Port Valve, automatically gets on when Blower on as pressed.

5.6.4 First seal the Container, then ON Atomizing, and in the last ON Blower ON Charging valve.

5.6.5 Charging Mode used for the loading of materials to the FBP bowl.

5.7 MAINTENANCE MODE:

5.7.1 Select the MAINTENANCE MODE from the MODE SELECTION on the Mode selection screen.

5.7.2 After selection click on MAINTENANCE MODE on the Mode selection screen all the alarm and maintenance related parameters are given.

5.8 SPRAY CHECK MODE:

5.8.1 Select the Spray check mode from the MODE SELECTION on the welcome screen.

5.8.2 Screen appears with peristaltic pumps ON/OFF options, Atomizing ON/OFF option.

5.8.3 Spray mode selected for the checking of spraying system.

5.9 Product Unloading:

5.9.1 Product unloading performs both auto and manual mode.

5.9.2 In the 'MANUAL MODE' screen firstly press the 'BAG SHAKING' then press 'UNSEAL' the container, to unseal the container.

5.9.3 Remove out the product bed temperature sensor.

5.9.4 Remove the product container.

5.9.5 Then unload the product in SS Bin lined with double polybag by swing on the SS shaft at the product container.

5.9.6 Press EXIT SCADA button to logout from the user and press the EMERGENCY SWITCH.

5.9.7 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).

5.10 Broken Bag Detector (BBD) Challenge Test:

5.10.1 Replace the 'CLEANED' label and affix 'EQUIPMENT STATUS label dully filled and signed on the equipment (In Case of cleaned equipment) Or it can perform during "Type-B" cleaning.

5.10.2 Take 200 grams of starch and put it in the FBP product bowl.

5.10.3 Start the FBP in Auto Mode.

5.10.4 The FBP should be tripped as the starch comes in contact with SFM.

5.10.5 After reset of BBD the machine can be start.

5.10.6 Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet) and in BBD Challenge test annexure-I (Broken Bag Detector Challenge Test).

5.10.7 Again take 200 grams of starch and put it in the FBP product bowl.

5.10.8 Start the FBP in Manual Mode.

5.10.9 The FBP should be tripped as the starch comes in contact with SFM.

5.10.10 After reset of SFM the machine can be start.

5.10.11 Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet) and in BBD Challenge test annexure-I (Broken Bag Detector Challenge Test).

5.10.12 After "BBD 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).

5.10.13 If 'BBD Challenge Test' not complies then inform to Production head and Maintenance head and after rectification again perform the 'BBD Challenge Test' and record the same in equipment usage log book.

5.10.14 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 IV (SFM sensor weekly cleaning record).

5.10.15 **Frequency**: First week of the Month.

5.10.16 For check the product trend, reports, events, parameters, audit trial report, alarm, batch wise audit report, batch wise alarm report and product recipe report, go to home screen then select all the icons individually, and check the report.

6.0 ABBREVIATION (S):

6.1 FBP : Fluidized Bed Processor

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 FC : Flow Control.

6.8 SFM : Solid Flow Monitor

6.9 SS : Stainless Steel

6.10 QA : Quality Assurance

6.11 SOP : Standard Operating Procedure

6.12 LH : Left Hand

6.13 RH : Right Hand

6.14 PBT : Product Bed Temperature

6.15 RPM : Round Per Minute

6.16 P & I : Program and Instrument

6.17 BBD : Broken Bag Detector

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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.

7.4 SOP: Cleaning and utilization of FBD finger bag and RMG filter bag.

7.5 SOP: Cleaning Validation.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	BBD (Broken Bag Detector) Challenge Test		Logbook
Annexure-II	Cleaning Checklist of Fluidized Bed Processor (APCG-450)		Logbook
Annexure-III	Retention screen Utilization and Cleaning Record		Logbook
Annexure-IV	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 I

BBD (Broken bag Detector) Challenge Test

FBP ID No.: _____ **YEAR: _____**

DATE	QTY. OF STARCH USED	ACTIVITY		CHALLENGE TEST AUTO MODE		CHALLENGE TEST MANUAL MODE		DONE BY	CHECKED BY	REMARKS
		FROM	TO	COMPLIES	NOT COMPLIES	COMPLIES	NOT COMPLIES			

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ANNEXURE II
CLEANING CHECKLIST OF FLUIDIZED BED PROCESSOR (APCG-450)

Name of the Equipment		**FLUIDIZED BED PROCESSOR (APCG-450)**	
Equipment ID No.		**Previous product**	
Batch No.		**Date**	

S.No.	Activity	Activity performed
1.0	Shake the finger bag in manually mode to de dust. (If applicable)	
2.0	Remove the remainants of the previous batch from the equipment and the area with a dry clean lint free duster.	
3.0	Clean the powder attached with the wall and return raiser with a dry clean lint free duster.	
4.0	Disconnect the Atomization and needle air pipes from the spraying guns and clean with a dry lint free duster.	
5.0	Disconnect the Product Bed Temperature (PBT) sensor & unseal the container, then remove the product bowl, swing out the expansion chamber and clean with a dry clean lint free duster to remove any leftover material.	
6.0	Unseal and bring down both right and left finger bag/ bonnet filter or retention screen by operating the finger bag/ bonnet filter or retention screen holding ring towards lower side by click on finger bag LH DOWN and RH DOWN on PLC.	
7.0	Clean the inside and outside of the retention screens with a dry lint free duster followed by compressed air.	
8.0	Remove the remainants of the previous batch from the equipment and the area with a dry clean lint free duster.	
9.0	Clean the powder attached with the wall and return raiser with a dry clean lint free duster.	
10.0	Dismantle the air channeliser to the product bowl by unclamped the toggle clamps.	
11.0	Remove the UP-bed and down bedplate, fine mesh and clean with a dry lint free duster.	
12.0	Dismantle the spraying system and clean with a dry lint free duster.	
13.0	Remove the finger bag rings from the finger holding coupling and clean the bags.	
14.0	Dismantle the air channeliser to the product bowl by unclamped the toggle clamps.	
15.0	Remove the UP-bed and down bedplate, fine mesh.	
16.0	Dismantle the spraying system.	
17.0	Remove the product bowl, and swing out the expansion chamber.	
18.0	Scrub the supporting plate with a nylon scrubber using purified water.	
19.0	Remove the inner partition, fine sieve, perforated bottom, sampling port & cup.	
20.0	Rinse the wurster container, inner partition with fixing components; fine sieve, perforated bottom, sampling port & cup with 60-80 liters of Purified water.	
20.1	**Note:** In case of coating solution contains enteric coating polymer/methacrylic acid then	

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S.No.	Activity	Activity performed
	repeat the step 5.2.12 with 60-80 litres 0.4 % NAOH solution and followed by with 60-80 litres purified water.	
21.0	Bring down the both two-finger bag or retention screens by operating the finger bag holding ring towards lower side.	
22.0	Remove the finger bag rings or retention screens from the finger holding coupling and clean the bags.	
23.0	Pull out the expansion chamber; dismantle the elliptical shaped observation window (1 nos.) of expansion chamber, elliptical shaped observation window (01 nos.) of product container bowl (top spray bowl & bottom spray bowl each) and viewing glass (2 nos.) of bag chamber.	
24.0	Scrub the expansion chamber and finger bag holder ring and view glasses with gasket, inflated gasket (5 nos.), and inflated tube ring with a nylon scrubber using purified water from inside and outside to remove any adhered material.	
24.1	Note**:** In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.16 with 0.4 % NAOH solution and followed by with purified water.	
25.0	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.	
26.0	Use the ladder to clean the outer surface bag chamber and expansion chamber.	
27.0	Rinse all the above parts with 60-70 liters of purified water.	
27.1	Note: In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.18 with 60-70 liters 0.4 % NAOH solution and followed by with 60-70 liters purified water.	
28.0	Scrub the product container bowl and trolley with a nylon scrubber using purified water.	
28.1	Note: In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.19 with 0.4 % NAOH solution and followed by with purified water.	
29.0	Scrub the sieve and supporting plate with nylon scrubber using 40-50 liters of purified water.	
30.0	Note: In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.20 with 40-50 liters 0.4 % NAOH solution and followed by with 40-50 liters purified water.	
31.0	Place the sieve and the supporting plate on a clean S.S. pellet. Reassemble the sieve and the supporting plate.	
32.0	**Method of cleaning of Spray system and corresponding tubes**	
32.1	Clean the solution feeding vessel with 10-20 liters of purified water.	
32.2	Take 50-60 liters of purified water in vessel.	
32.3	Removes the product inlet and outlet tubes from the nozzles of the solution-feeding vessel.	
32.3	Dip the tubes into purified water.	
32.4	Reduce the atomizing air pressure to zero.	

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S.No.	Activity	Activity performed
32.5	Run the peristaltic pump at high speed.	
32.6	Continue this till fresh water comes out from the spray guns.	
32.7	Dismantle the spray gun and clean with a dry lint free duster.	
32.8	Unscrew the four hex bolts and then remove the spraying assembly from the FBP.	
32.9	Flush the tubes with 50 liters of purified water.	
32.10	Remove the nozzle from the spray gun.	
33.0	**Method of cleaning of Retention Screens/ Finger bag**	
33.1	Bring down the both two-finger bag or retention screens by operating the finger bag holding ring towards lower side.	
33.2	Remove the finger bag rings or retention screens from the finger holding coupling and	
33.3	Rinse the retention screens with 20-25 liters of purified water.	
33.4	Scrub the inside and outside of the screens with nylon scrubber using 25-30 liters of purified water.	
33.4.1	Note: In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.23.2 with 25-30 liters 0.4 % NAOH solution and followed by with 25-30 liters purified water.	
33.5	Rinse and wash the retention screens with sufficient quantity of purified water.	
34.0	Scrub the outside of the FBP, supporting arms inlet air duct and the inlet chamber with a nylon scrubber using 40-50 liters of purified water.	
34.1	Note: In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.24 with 40-50 liters 0.4 % NAOH solution.	
35.0	Clean the outer surface of FBP; supporting arms inlet air duct and inlet air chamber with 10-20 liters of purified water.	
36.0	Clean the utility cables limit switches and control panel with a dry lint free duster.	
37.0	Reassemble the observation window of product container, expansion chamber and bag chamber.	
38.0	Put the cleaned FBP finger bag in FBP bowl on top spray FBP bowl.	
39.0	Assemble the FBP and operate the FBP 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.	
40.0	Rinse the FBP product bowl, bag chamber, expansion chamber and view glasses with 50-60 liters of purified water.	
41.0	Wipe out the body of FBP, bag chamber, expansion chamber, trolley and bowl with a clean dry lint free duster.	
42.0	Wipe all the above parts with 70% v/v IPA solution.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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

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ANNEXURE III

RETENTION SCREEN UTILIZATION AND CLEANING RECORD

DEPARTMENT: **MONTH/YEAR:**

Retention Screen Size:

Date	Retention Screen Code No.	Product	Batch No.	Activity	Checked By	Remarks

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ANNEXURE IV
SFM SENSOR WEEKLY CLEANING RECORD

DATE	CLEANING		DONE BY	CHECKED BY	REMARKS
	FROM	TO			