



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Auto Coater (Bectochem)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

To lay down a procedure for the Cleaning and operation of Auto Coater Bectochem (BLC-120/BLC-150)

2.0 SCOPE:

This procedure is applicable to cleaning and operation of Auto coater Bectochem (BLC-120/BLC-150) located in manufacturing area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Production Officer / Executive: Checking cleaning

Head Production : SOP Compliance

IPQA Person : Line Clearance

4.0 DEFINITION (S):

NA.

5.0 PROCEDURE

5.1 "TYPE A" CLEANING: This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.

5.1.1 Replace 'To be Cleaned 'status label with "Under Cleaning" status label from the equipment.

5.1.2 Ensure that power supply is turned "OFF".

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

5.1.4 Clean the main control panel and stand of the panel with a dry lint free cloth.

5.1.5 Clean exhaust duct, Inlet duct, view glass and pan door with the help of dry lint free cloth.

5.1.6 Clean the pan with the help of dry lint free cloth.

5.1.7 Clean the side covers of the Auto-Coater with the help of dry lint free cloth.

5.2 "TYPE B" CLEANING: This is a cleaning procedure for Changeover of product with different actives/color/ascending potency/descending potency or after maintenance of contact parts.

5.2.1 Follow the step no.5.1.1 to 5.1.4.

5.2.2 Cover the control panel with polybag to avoid water entry.



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- 5.2.3 De-dust the equipment with dry lint free cloth.
- 5.2.4 Open the valve of the waste water outlet.
- 5.2.5 Flush the solution holding tank with 20-30 liters of purified water with pressure jet cleaner. Scrub the tank with nylon scrubber to remove the adhered material. Rinse the tank with 20 liters. of purified water.
- 5.2.6 Fill the solution holding tank with 40 liters of purified water with pressure jet cleaner. Flush the water using the peristaltic pump in level 3.
- 5.2.7 Simultaneously rubbing the solution pipes with hand to remove the adhered inside material. Check the cleaning of pipes
- 5.2.8 Again flush 40 liters of purified water through peristaltic pump, solution pipes and finally through spray guns and nozzles assembly.
- 5.2.9 Open the side panels of Auto coater. Remove the inlet and outlet ducts.
- 5.2.10 Start rotation of the pan at slow speed. Now start the cleaning of the pan with 300 liters of purified water from inside with the help of pressure jet cleaner. By using nylon scrubber if required. Also ensure the proper cleaning of the baffles.
- 5.2.11 Clean the both sides (inlet duct side and outlet duct side) of the pan with 300 liters of purified water with pressure jet cleaner. Use nylon brush for scrubbing the adhered material on either side if required.
- 5.2.12 Clean both the ducts with 200 liters of purified water with pressure jet cleaner. Use nylon brush simultaneously for scrubbing the adhered material if required.
- 5.2.13 Finally rinse the inside of the pan, outside of the pan and inlet and outlet ducts with 200 liters of purified water by using pressure jet cleaner.
- 5.2.14 Clean the bottom surface of the machine below the pan with 200 liters of purified water by using pressure jet cleaner.
- 5.2.15 Dismantle the spray assembly from equipment and clean with 15-20 liters of purified water. Scrub it with nylon brush to remove the adhered material. Then rinse it with 10-15 liters purified water.
- 5.2.16 Dismantle the guns from assembly and clean the nozzles and caps with wet lint free cloth. Use nylon brush for scrubbing if required.
- 5.2.17 In case of previous product API is Efavirenz clean the cleaned parts and equipment surface with 2% sodium lauryl sulfate before final rinsing.
- 5.2.18 In case enteric coated material like Methacrylic acid is used for coating solution; clean the cleaned parts and equipment surface with 0.4% sodium hydroxide solution before final rinsing.
- 5.2.19 Finally rinse the nozzles and caps with 5-10 liters of purified water.
- 5.2.20 Start the hot air and exhaust for complete drying of the pan after complete assembly of machine.



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- 5.2.21 Note: - Close the water system after completion of cleaning.
- 5.2.22 Clean view glass, pan door and side covers with the help wet lint free cloth.
- 5.2.23 Dry all other parts with dry lint free cloth.
- 5.2.24 Wipe all the parts of the equipment with 70% v/v IPA.
- 5.2.25 Assemble all the dismantled parts of the equipment.
- 5.2.26 Replace the 'Under Cleaning' status label with duly signed "CLEANED" label by production and QA officer after cleaning on the equipment.
- 5.2.27 Record the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.28 Record the cleaning activity in Annexure-I (Cleaning checklist of Auto coater (BLC-120/BLC-150)).
- 5.2.29 Check the equipment for visual cleanliness and inform QA department for Swab sampling, if required.

5.3 Frequency:

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product, same 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, de-dusting of machine with vacuum cleaner or dry by lint free cloth.
- 5.3.4 **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 Machine Setting:

- 5.4.1 Ensure that the equipment and area is cleaned. Get line clearance from QA personal.
- 5.4.2 Remove CLEANED label from the equipment.
- 5.4.3 Record the start time in the Equipment Usage Log Sheet as per SOP.
- 5.4.4 Ensure that the compressed air and main electric supply is 'ON' from service area.
- 5.4.5 Ensure discharge valve is closed.
- 5.4.6 Ensure that Compressed air pressure on pressure gauge is approximately 04 bar.



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5.5 Operation:

There are three levels of Operation:

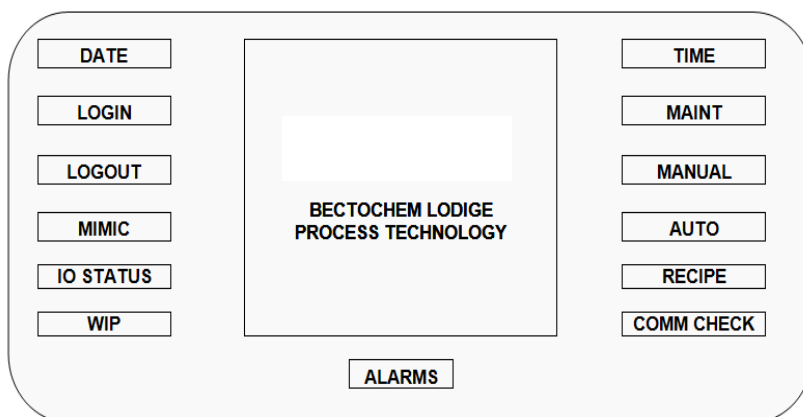
Level 1. Operator can operate machine in auto mode after the recipe has been loaded from recipe mode and can use the existing recipe loaded in HMI.

Level 2. Supervisor can operate machine in auto/manual mode and can load existing recipe from recipe mode.

Level 3. Manager can operate the machine in maintenance mode, can create/edit/Delete recipe from HMI.

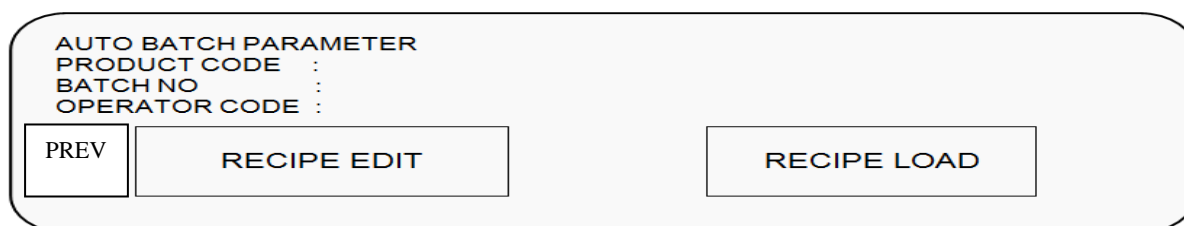
5.5.1 RECIPE LOAD/EDIT:

5.5.1.1 Turn on the coater by rotating the selector switch to 'ON' position on control panel. The screen will appear as:



5.5.1.2 Press LOGIN to login and enter correct password with the help of touch key pad on the screen and press RECIPE for edit, load or delete a recipe.

5.5.1.3 After pressing recipe screen will appear as:



5.5.1.4 Press RECIPE EDIT and screen will appear as:



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RECIPE EDIT-1
CURRENT RECIPE NAME
SET

PAN RPM FOR DEDUSTING	___
PAN RPM FOR SPRAYING	___
PAN RPM FOR DRYING	___
PRE JOG ON TIME	___
PRE JOG OFF TIME	___
NO. OF PRE JOG CYCLE	___
NO. OF DOSING CYCLE	___
SPRAY PUMP SPEED	___
SPRAY ON TIME	___
SPRAY OFF TIME	___
DRYING TIME	___
COOLING TIME	___

PRE NEXT

5.5.1.5 Set the above parameters as per requirement of batch and press NEXT on screen. Next screen will appear as

RECIPE EDIT-2

PERIODIC PRINT INTERVAL	SET	___
RH SET	___	
RH HIGH SET	___	
DP ACROSS CABINET HIGH SET	___	
INLET BLOWER SPEED	___	
EXHAUST BLOWER SPEED	___	
DP ACROSS HEPA HIGH	___	
INLET DAMPER OPENING	___	
EXHAUST DAMPER OPENING	___	
BED TEMP HIGH SET	___	
BED TEMP LOW SET	___	

PREV NEXT

5.5.1.6 Set the above parameters as per requirement of batch and press NEXT on screen. Next screen will appear as:

RECIPE EDIT-3

<u>PROCESS</u>	SET	
INLET TEMP SET	___	
INLET TEMP HIGH SET	___	
EXHAUST TEMP HIGH SET	___	
EXHAUST TEMP LOW SET	___	
<u>DRYING</u>		
INLET TEMP SET	___	
INLET TEMP HIGH SET	___	
EXHAUST TEMP HIGH SET	___	
EXHAUST TEMP LOW SET	___	

PREV NEXT

5.5.1.7 Set the above parameters as per requirement of batch and press NEXT on screen. Next screen will appear as:



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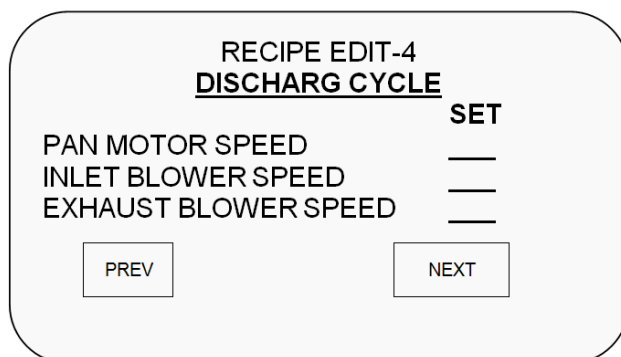
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5.5.1.8 Press NEXT to see all the set parameters in the recipe:

5.5.1.9 Press SAVE on screen to save the recipe or press DELETE to delete recipe.

5.5.1.10 Press EXIT to exit from the RECIPE.

5.5.1.11 To load a recipe first edit the recipe to be loaded and then press LOAD RECIPE to load the required recipe.

5.5.1.12 Press EXIT, home screen will appears.

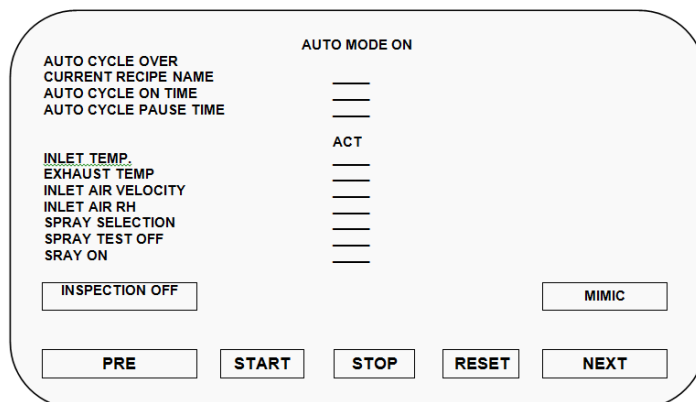
5.5.2 AUTO MODE OPERATION

5.5.2.1 Load the uncoated tablets in the coating pan.

5.5.2.2 Transfer the coating solution from solution preparation tank to solution holding tank.

5.5.2.3 For auto mode operation press AUTO on the screen in MMI.

5.5.2.4 Following screen will appears:



5.5.2.5 Press START to start a cycle of loaded recipe or press STOP to stop the running cycle.

5.5.2.6 Start the spraying cycle, solution will come out through spraying nozzle and spray over tablet bed.

5.5.2.7 Press RESET to restart the cycle.



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5.5.2.8 Press NEXT to see all the parameters set in the recipe of the running cycle.

5.5.2.9 The screen which appears after pressing NEXT will show the actual parameters at that time of the coating running cycle.

5.5.2.10 Press EXIT to exit from the auto mode.

5.5.3 MANUAL MODE OPERATION:

5.5.3.1 Press MANUAL on the home screen for manual mode operation.

5.5.3.2 Add product code, batch no, and operators code and press NEXT.

5.5.3.3 Load the tablets to be coated in the coater pan.

5.5.3.4 Transfer the coating solution from solution preparation tank to solution holding tank.

5.5.3.5 Press NEXT after setting all the parameters on the screen as per respective BMR. Following screen will appear:

MANUAL MODE ON

INLET TEMP SET	_____
INLET TEMP HIGH SET	_____
EXHAUST TEMP HIGH SET	_____
EXHAUST TEMP LOW SET	_____
BED TEMP HIGH SET	_____
BED TEMP LOW SET	_____
RH SET	_____
RH HIGH SET	_____
PAN SPEED	_____
PAN JOG SPEED	_____

PREV MIMIC NEXT

5.5.3.6 Touch on the above parameters to ON or OFF them as per requirement of the coating procedure as per respective BMR.

5.5.3.7 Press NEXT and turn on or off the following parameters for coating:

MANUAL MODE ON

LAMP ON/OFF
SPRAY TEST ON/OFF
SPRAY JOG OFF/ON
PAN MOTOR ON/OFF
DUST COLLECTAR ON/OFF
INLET BLOWER ON/OFF

PREV MIMIC EXIT



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5.5.3.8 To see all the parameters set for manual coating press STEAM on the screen.

5.5.3.9 Press EXIT, home screen will appear.

5.5.3.10 Unload the coated tablets after completion of process to the pre-labeled SS/HDPE containers.

5.5.3.11 Put 'To Be Cleaned' Label in the equipment after completion of coating activity.

5.5.4 PRECAUTION:

5.5.4.1 While operating the system the following precautions have to be taken.

5.5.4.2 Check the connection of silicon tube from vessel to gun through peristaltic pump.

5.5.4.3 Check all the connection of silicon tube to gun. Adjust the gun to desired angle and

5.5.4.4 Distance inside the pan.

5.5.4.5 Check correct direction of rotation of Pan clockwise when viewed from the front.

5.5.4.6 The exhaust should be on before turning the hot air blower.

5.5.4.7 Check the zero error of magnehelic gauge by opening the door of coater.

5.5.5 Pressure inside the pan should be negative and is indicated by a differential pressure gauge fixed on the cabinet. If this pressure is not negative either the supply is more or the exhaust is less. Record the coater differential pressure and zero error as per Annexure- I (Cleaning checklist of Auto coater (BLC-120/BLC-150)).

5.5.5.1 The drain outlet water valve for washing should always be closed during operation and only opened while washing the machine.

5.5.5.2 Turn off the steam supply before turning off the blower. After 5 minutes, turn off the hot air blower and lastly turn off the exhaust.

5.5.5.3 Turn off the air only after turning off the peristaltic pump. Otherwise excessive pressure may build up in the tubing causing damage to it. The air should be allowed to be on for few seconds after the peristaltic pump is switched off in order to clean the gun.

6.0 ABBREVIATION (S):

PRT - Production Tablet

SOP - Standard Operating Procedure

V/V - volume/volume

IPA - Iso Propyl Alcohol.

SS - Stainless Steel

HDPE - High Density poly ethylene.

HMI - Human Machine Interference

MMI - Man Machine Interference



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7.0 REFERENCE (S):

SOP: Status Labeling.

SOP: Cleaning in Production Area.

SOP: Making entries in Equipment usage and Cleaning Log Sheet.

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format no.	Mode of Execution
Annexure-I	Cleaning Checklist of Auto coater (BLC-120/BLC-150).		Log Book

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

Controlled Copy (S) : Production department (02), Quality Assurance (01)

Reference Copy (S) : Production department (04)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
1.	00		New SOP	NA	04/16



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ANNEXURE -I

CLEANING CHECKLIST OF AUTO COATER BECTOCHEM

Name of the Equipment		Auto Coater Bectochem	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity		Activity Performed
1.	Flush the solution holding tank with 20-30 liters of purified water with pressure jet cleaner. Scrub the tank with nylon scrubber to remove the adhered material. Rinse the tank with 20 liters. of purified water		
2.	Fill the solution holding tank with 40 liters of purified water with pressure jet cleaner. . Flush the water using the peristaltic pump in level 3 (Maintenance mode).		
3.	Again flush 40 liters of purified water through peristaltic pump, solution pipes and finally through spray guns and nozzles assembly		
4.	Start rotation of the pan at slow speed. Now start the cleaning of the pan with 300 liters of purified water from inside with the help of pressure jet cleaner. by using nylon scrubber if required. Also ensure the proper cleaning of the baffles		
5.	Clean the both sides (inlet duct side and outlet duct side) of the pan with 300 liters of purified water with pressure jet cleaner use nylon brush for scrubbing the adhered material on either side if required.		
6.	Clean both the ducts with 200 liters of purified water with pressure jet cleaner. Use nylon brush simultaneously for scrubbing the adhered material if required.		
7.	Finally rinse the inside of the pan, outside of the pan and inlet and outlet ducts with 200 liters of purified water by using pressure jet cleaner		
8.	Clean the bottom surface of the machine below the pan with 200 liters of purified water by using pressure jet cleaner.		
9.	Dismantle the spray assembly from equipment and clean with 15-20 liters of purified water. Scrub it with nylon brush to remove the adhered material. Then rinse it with 10-15 liters purified water.		
10.	Dismantle the guns from assembly and clean the nozzles and caps with wet lint free cloth. Use nylon brush for scrubbing if required. Finally rinse the nozzles and caps with 5-10 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. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)		(incase of Efavirenz)
12.	Incase enteric coated material like methacrylic acid is used for coating solution, clean the cleaned parts and equipment surface with 0.4% sodium hydroxide solution before final rinsing.		(incase of enteric coating)
13.	Start the auto coater for sufficient time at 70 °C to dry the pan.		



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14.	Disconnect the solution supply pipes and clean with purified water and 70% v/v IPA Solution and finally dry them with compressed air. (If required the supply tubes may be dried in pan at 70 °C for sufficient time.	
15.	Ensure that pan is dried properly.	
16.	Stop the auto coater.	
17.	Wipe the inner and outer surface of solution tank, pan, sides and top of with 70 % w/w IPA.	

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/date