



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Multi Pan Ganscoater	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Multi-Pan Ganscoater.

2.0 SCOPE:

2.1 This SOP is applicable to the Cleaning and Operation of Multi-Pan Ganscoater and its accessories in the production area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation
- 3.2 Officer and Executive : Supervision
- 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:

This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.

- 5.1.1 First affix 'UNDER CLEANING' label on the machine and record the cleaning start time in the equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.1.2 Dedust the external surface of auto coater, dedust the pan with lint free cloth (if required).
- 5.1.3 Dedust the pan with lint free cloth to remove any adhere material and finally start the exhaust for 5 minute to remove the dust of previous batch.
- 5.1.4 Collect the remaining quantity of coating solution from the solution tank in a double polybag and send it to ETP with disposed tablets.
- 5.1.5 Rinse the solution tank with excess quantity of purified water to remove the previous adhere material.
- 5.1.6 Clean the spray guns and solution supply pipe by flushing the excess quantity of purified water through hem. And dismantle the solution supply pipes and dry them with compressed air.
- 5.1.7 After then remove the spray nozzle and clean with nylon brush or wet lint free duster to remove the adhere coating material. Finally rise with water or 70 % V/V IPA as required.
- 5.1.8 Clean the area as per SOP "Cleaning of Production Area".



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5.1.9 Replace the “UNDER CLEANING” label of machine with “CLEANED” status label and record the cleaning end time in the 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/ascending potency / descending potency or after maintenance of contact parts.

5.2.1 First affix ‘UNDER CLEANING’ label on the machine and record the cleaning start time in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

5.2.2 Cover the control panel, peristaltic pump, air motor of solution tank and balance with Poly bags to avoid water entry into them.

5.2.3 Collect the remaining quantity of coating solution from the solution tank in a double polybag and send it to ETP with disposed tablets.

5.2.4 Clean the solution tank with excess quantity of purified water to remove the previous adhere material. If required scrub the tank with nylon scrubber to remove the adhere material and finally clean with purified water.

5.2.6 Fill the solution tank with 20 kg of purified water.

5.2.7 Connect the WIP connector to the machine.

5.2.8 Turn ‘ON’ the MMI/PLC. The main screen displays.

5.2.9 Release the atomization pressure to zero by gauge.



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Select the "MENU" from main screen, it displays menu screen

DATE	TIME
SELECT MENU	
MAIN	ALARM
PASS WORD	PARAMETRS
RECIPE	CONTROL PANNEL
TREND	M/C DATA
HOT WATER PID	CHECK LIST

- 5.2.10 Press PASSWORD option in menu and enter the password. And press "EXIT" to come to menu screen.
- 5.2.11 Press the "CONTROL PANNEL" the machine mode screen displays. Press the machine mode to select "AUTO"/ "MAINTENANCE" Mode. Select the "MAINTENANCE" mode.
- 5.2.12 In "MAINTENANCE MODE" the four screens comes by pressing the arrow key on right top respectively, i.e.
- Blower screen
 - Dosing Pump screen
 - Scrubber Pump screen
 - WIP Screen
- 5.2.13 Select the "WIP" screen, and start the WIP pump.
- 5.2.14 The WIP pump delivers the purified water to the machine.
- 5.2.15 After starting WIP pump, start the coating pan and dosing pump.
- 5.2.16 Purified water coming via spray nozzles through WIP pump wets the coating pan.
- 5.2.17 Open the side panels and unbolt all baffles from the Pan inside.
- 5.2.18 The sink provided at the bottom of the pan shall be filled with purified water. Rotating the drum through purified water contained in the sink shall clean the pan.
- 5.2.19 Follow the instruction given in MMI Parameter and start the cleaning.
- 5.2.20 **Method of cleaning in case of coating solution contains enteric coating polymer/ methacrylic acid:**



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- 5.2.21 Repeat the step 5.2.18 and 5.2.19 with sink filled by 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.18 and 5.2.19 with purified water.
- 5.2.22 The dosing pump delivers the purified water from solution tank to coating guns via delivery pipes. By this the remaining coating solution in delivery pipes and in guns comes out.
- 5.2.23 Ensure that whole pan has wet properly and then STOP the pan and WIP pump.
- 5.2.24 Scrub the pan and baffles with nylon brush to soften the adhered matters.
- 5.2.25 Open the left side and right side pan wall screw and dismantle both side covers.
- 5.2.26 Remove the right side plenum and left side plenum by unlock the clamps provided.
- 5.2.27 Clean the both plenums with lint free cloth dipped in purified water. Clean the inlet and exhaust blower passage with lint free cloth dipped in purified water.
- 5.2.28 Dismantle the baffles and clean with nylon brush followed by purified water to remove all the adhered material on the baffles.
- 5.2.29 Clean the inner wall of the auto coater with the lint free cloth dipped in purified water.
- 5.2.30 After that clean the drain point from inside and outside with the lint free cloth dipped in purified water.
- 5.2.31 Clean the plenums with the help of nylon scrubber and purified water.
- 5.2.32 Mount the side wall of the pan and tight with the screw provided on the both sides.
- 5.2.33 Ensure the sharp edges of baffles, inlet and exhaust ducts and plenums have been cleaned properly.
- 5.2.34 "START" the WIP pump till all the adhered and soften matters washed away.
- 5.2.35 In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.19 with 50-70 liters 0.4 % NAOH solution and followed by with 50-70 liters purified water.
- 5.2.36 Start the inlet and exhaust blower for 30-40 minutes to dry the pan at 70 °C.
- 5.2.37 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 30-40 minutes).
- 5.2.38 Disassemble the guns and clean the each part of gun with purified water. After then Clean the guns and its parts with 70 % v/v IPA solution and nylon bush brush to remove the any color residue. Finally dry the guns and their parts with compressed air.
- 5.2.39 Disconnect the compressed air supply to solution tank. Flush the solution tank with purified water till whole contains of previous product are washed away.
- 5.2.40 Dry the solution tank with clean lint free cloth.



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- 5.2.41 Open the side cover to check the cleanliness of inlet and exhaust plenums, if any previous color or adhere material seems clean it with the help of wet lint free cloth. After cleaning assemble the both plenums.
- 5.2.42 Clean the inner wall of auto coater with 70% v/v IPA.
- 5.2.43 Clean the auto coater drain with lint free cloth dipped in purified water followed by 70% v/v IPA.
- 5.2.44 Clean the sides and top of auto coater with clean wet lint free cloth.
- 5.2.45 Mount the side wall of the pan and tight with the screw provided on the both sides.
- 5.2.46 Ensure that pan is dried properly.
- 5.2.47 Wipe the inner and outer surface of solution tank, pan, sides and top of with 70 % V/V IPA.
- 5.2.48 Dedust the control panel, peristaltic pump with clean lint free cloth.
- 5.2.49 Intimate to Engineering department for replacing the water of wet scrubber unit with fresh water.
- 5.2.50 Clean the area as per SOP "Cleaning of Production Area".
- 5.2.51 Affix 'CLEANED' label duly filled and signed on the equipment.
- 5.2.52 Record the cleaning observations in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.2.53 The machine shall be cleaned within 24 hours after use.

5.3 Frequency:

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week 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 Machine Setting in Auto Mode

- 5.4.1 Turn the 'ON' the EMERGENCY.
- 5.4.2 Turn "ON" the Pan Light switch on control panel to "ON" position.
- 5.4.3 Turn "ON" the "PLC/MMI" MMI displays the main screen (as step no. 5.2.9).



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- 5.4.4 Press "PASSWORD" option in menu and enter the password. And press "EXIT" to come to menu screen.
- 5.4.5 Press the "CONTROL PANNEL" the machine mode screen displays. Press the machine mode to select "AUTO/ "MAINTENANCE" Mode. Select the "AUTO" mode.
- 5.4.6 Come to "SELECT MENU" screen and select "PARAMETER"
- 5.4.7 Temperature Parameter screen will open it shows:
* Recipe: it comes automatically as selection of recipe
* Product Code: Enter the Product Code
* Batch No.: Enter the batch no.
* Operator code: Enter the Operator code
* Product Name: Enter the product name
- 5.4.8 * Inlet Air temperature SP : __ ° c (as per BMR)
* Inlet Air temp. max. + ve : __ ° c
* Exhaust Air temperature SP : _____ ° c (as per BMR)
* Exhaust Air temp. + ve : __ ° c
- 5.4.9 Go to next screen by pressing the → key on top the General parameter displays
* Inlet Air Blower: __rpm. (As required)
* Exhaust Air Blower: __rpm. (As required)
* Solution Tank temp. SP : __
* Pan Speed : __
* HEPA filter DP : __
* Automising Air Pressure : __
* Agitator On time : __
* Agitator Off time : __
* Print Interval : __
- 5.4.10 Go to next screen by pressing the → key on top the Pre Jog parameter displays
* Pan On Time : __Sec. (As required)
* Pan Off Time : __Sec. (As required)
* No. of Cycles : __Sec. (As required)
* Inlet Air temperature SP : __ ° c (as per BMR)
* Exhaust Air temperature SP : _____ ° c (as per BMR)



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5.4.11 Go to next screen by pressing the → key on top the Dosing Pump Parameter displays

* Set Speed : __rpm (as per BMR)

* At Bed Temp.: __° c

* Rate of change: __

5.4.12 Go to next screen by pressing the → key on top the Film Mode Dosing Parameter displays

* Dosing Off Time : __Sec. (As required)

* Dosing On Time .: __ Sec. (As required)

* No. Of Dosing Cycle : __

5.4.13 After putting all above parameters come to the main screen.

5.5 Machine Setting in Manual/Maintenance Mode

5.5.1 Follow the steps 5.3.1 to 5.3.4.

5.5.2 Follow the steps 5.3.6 to 5.3.9.

5.5.3 Come to the “SELECT MENU” as shown in step no. 5.2.9.

5.5.4 Select the “CONTROL PANEL” and the select the maintenance mode AS STEP 5.3.5.

5.5.5 In “MAINENANCE MODE” the four screens comes by pressing the arrow key on right top respectively, i.e.

a) Blower screen

b) Dosing Pump screen

c) Scrubber Pump screen

d) WIP Screen

5.5.6 First start the scrubber pump, Exhaust blower, Inlet blower, Pan and Dosing pump respectively.

5.5.7 After putting all above parameters come to the main screen.

5.5.8 After completion of dosing stop the machine in descending order as per Step no.5.4.6.

5.5.9 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 OPERATION

5.6.1 Ensure that the equipment and area is cleaned as per SOP “Cleaning of Production area”. Affix ‘UNDER PROCESS’ label dully filled and signed on the equipment and record the in the Equipment Usage Log as per SOP “Making entries in equipment usage and cleaning log sheet”.

5.6.2 Ensure that the compressed air and main electric supply is ‘ON from service area.



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- 5.6.3 Ensure that Compressed air pressure on pressure gauge is NLT 0.2 Mpa.
- 5.6.4 Select the desired pan as per batch size from below mentioned pan.
- 5.6.5 Assemble the baffles to the pan (For 24 inch) as per instruction given in the BMR that is Rabbit ear type or Plug type. If there is no instruction in BMR for the baffles then Plug type baffles to be used.
- 5.6.6 For 36 inch pan baffles to be used as per instruction given in BMR, If there is no instruction in BMR for the baffles then Antisliding type baffle to be used.
- 5.6.7 Follow the step 5.2.9 to 5.2.11. The Retractable IN / OUT screen displays. Press OUT to bring out the Retractable Arm.
- 5.6.8 Open the front cover and both side plenum covers.
- 5.6.9 First disassemble the inlet and exhaust plenum. Then open the screw of shaft on which pan is mounted.
- 5.6.10 Pull out the pan with the help of pan holding trolley.
- 5.6.11 Mount the desired pan 18 inches or 24 inches or 36 inches as per batch size (as mentioned in BMR), with the help of trolley. As per Format.
- 5.6.12 Attach the inlet and exhaust plenum of pan in the machine. And bolt the plenum cover.
Note: Check that the Teflon screwed with inlet and exhaust plenum of pan and plenum fitted to the pan properly.
- 5.6.13 Close the outer cover of machine.
- 5.6.14 Check the spray rate, displayed on the PLC.
- 5.6.15 Load the core tablets in the pan. And Put the retractable arm in by pressing “IN” option on Retractable Arm screen displays.
- 5.6.16 Fix the bed temperature sensor and Close the view window of auto coater.
- 5.6.17 Load the coating solution in the solution tank before loading the tablets. During loading of coating solution ensure that discharge valve of solution tank is closed.
- 5.6.18 Set the agitator on and off time in general parameter screen as per step no. 5.3.9.
- 5.6.19 Set the supply air and exhaust air temperature as specified in respective BMR as per step no 5.3.8
- 5.6.20 Set the pan rpm, Inlet blower and exhaust blower rpm as per specified in BMR by going as per step no. 5.3.8.
- 5.6.21 Set the atomizing air pressure, print interval (if required), prejog and dosing pump parameters as per BMR by going as per step no. 5.3.8 to 5.3.12
- 5.6.22 After setting of all required parameters, select the “AUTO” mode as per step no. 5.2.11.
- 5.6.23 Come to the main screen by pressing the “MAIN” in select menu.
- 5.6.24 In “MAIN SCREEN” press the “FILM START” to start the coating process.



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- 5.6.25 Press the MAIN. Display shows the all the parameters like Inlet Temperature, Exhaust temperature, Bed temperature, Pan RPM, Dosing RPM, % RH, and Tank weight and Spray rate of the coating solution spray.
- 5.6.26 On completion of total dosing cycle coating process stops automatically or if desired weight of tablet is achieved press the “AUTO STOP” on main screen to stop the process.
- 5.6.27 Open the view window and adjust the bed temperature sensor such that it does not touch The pan mouth while retractable arm is coming out.
- 5.6.28 Follow the step no. 5.4.5, to bring out the retractable arm.
- 5.6.29 Place the discharge chute to the mouth of pan to unload the tablets and close the door. Place clean pre-labeled, double polybag lined SS bin below the discharge. Turn ON the pan. Discharge will start.
- 5.6.30 For unloading start the pan in manual mode to unload the tablets.
- 5.6.31 Ensure the pan is discharged completely.
- 5.6.32 After unloading of tablets switch off the MMI/PLC, Pan light and finally press the emergency switch.
- 5.6.33 Affix ‘TO BE CLEANED label duly filled and signed on the machine and record the observations in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

6.0 Format (S):

Format no.	Title of Format	Format/ Template	Usage type
	Cleaning Checklist	Format	Bounded book
	Coating Pan Details	Format	Computerized usage

7.0 ABBREVIATION (S):

- 7.1 IPA : Iso Propyl Alcohol
- 7.2 SOP : Standard Operating Procedure
- 7.3 v/v : Volume/Volume
- 7.4 BMR : Batch Manufacturing Record
- 7.5 MMI : Man Machine Interface
- 7.6 PLC : Programmable Logical Control
- 7.7 Mpa : Milipascal
- 7.8 WIP : Wash In Place



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- 7.9 Sec. : Seconds
- 7.10 rpm : Rotation Per Minute
- 7.11 °C : Degree centigrade
- 7.12 ETP : Effluent Treatment Plant
- 7.13 RPM : Round Per Minute
- 7.14 RH : Relative Humidity

8.0 REFERENCES (If any):

- 8.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 8.2 SOP: Cleaning of Production Area.
- 8.3 SOP: Status Labeling



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ANNEXURE I CLEANING CHECKLIST

Name of the Equipment		GANSCOATER	
Equipment I.D. No.		Previous product	
Batch No.		Date	
S. No	Activity		Activity Performed
1.	Wet the pan properly with the help of WIP pump.		
2.	Scrub the pan with nylon brush to soften the adhered matters		
3.	After starting WIP pump, start the coating pan and dosing pump.		
4.	Purified water coming via spray nozzles through WIP pump wets the coating pan.		
5.	The dosing pump delivers the purified water from solution tank to coating guns via delivery pipes. By this the remaining coating solution in delivery pipes and in guns comes out.		
6.	Ensure that whole pan has wet properly and then STOP the pan and WIP pump.		
7.	Scrub the pan and baffles with nylon brush to soften the adhered matters.		
8.	Open the left side and right side pan wall screw and dismantle both side covers.		
9.	Remove the right side plenum and left side plenum by unlock the clamps provided.		
10.	The sink provided at the bottom of the pan shall be filled with purified water. Rotating the drum through purified water contained in the sink shall clean the pan.		
11.	Follow the instruction given in MMI Parameter and start the cleaning.		
12.	Repeat the step filled by 0.4 % NAOH solution instead of purified water and finally repeat the step with purified water.		
13.	The dosing pump delivers the purified water from solution tank to coating guns via delivery pipes. By this the remaining coating solution in delivery pipes and in guns comes out.		
14.	Clean the both plenums with lint free cloth dipped in purified water. Clean the inlet and exhaust blower passage with lint free cloth dipped in purified water.		
15.	Dismantle the baffles and clean with nylon brush followed by purified water to remove all the adhered material on the baffles.		
16.	Clean the inner wall of the auto coater with the lint free cloth dipped in purified water.		
17.	Clean the drain point from inside and outside with the lint free cloth dipped in purified water.		



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S. No	Activity	Activity Performed
18.	Clean the plenums with the help of nylon scrubber and purified water.	
19.	Mount the side wall of the pan and tight with the screw provided on the both sides.	
20.	Ensure the sharp edges of baffles, inlet and exhaust ducts and plenums have been cleaned properly.	
21.	“START” the WIP pump till all the adhered and soften matters washed away.	
22.	In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.19 with 50-70 liters 0.4 % NAOH solution and followed by with 50-70 liters purified water.	
23.	Start the inlet and exhaust blower for 30-40 minutes to dry the pan at 70 °C.	
24.	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 30-40 minutes).	
25.	Disassemble the guns and clean the each part of gun with purified water. After then Clean the guns and its parts with 70 % v/v IPA solution and nylon bush brush to remove the any color residue. Finally dry the guns and their parts with compressed air.	
26.	Disconnect the compressed air supply to solution tank. Flush the solution tank with purified water till whole contains of previous product are washed away.	
27.	Dry the solution tank with clean lint free cloth.	
28.	Open the side cover to check the cleanliness of inlet and exhaust plenums, if any previous color or adhere material seems clean it with the help of wet lint free cloth. After cleaning assemble the both plenums.	
29.	Clean the inner wall of auto coater with 70% v/v IPA.	
30.	Clean the auto coater drain with lint free cloth dipped in purified water followed by 70% v/v IPA.	
31.	Clean the sides and top of auto coater with clean wet lint free cloth.	
32.	Mount the side wall of the pan and tight with the screw provided on the both sides.	
33.	Ensure that pan is dried properly.	
34.	Wipe the inner and outer surface of solution tank, pan, sides and top of with 70 % V/V IPA.	
35.	Dedust the control panel, peristaltic pump with clean lint free cloth.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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



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ANNEXURE II SCREEN PAN DETAIL

Pan Size Details			
S.No.	Pan Size	Pan Number	Perforation Size
1.	18 inches	PAN/18/01	2.5 mm
2.	24 inches	PAN/24/01	2.5 mm
3.	36 inches	PAN/36/01	2.5 mm
4.	36 inches	PAN/36/03	1.6 mm

Details of Specific Product Used in Pan			
S.No.	Pan Size	Pan Number	Product Used For
1.	36 inches	PAN/36/03	Dimethyl Fumarate Tabs