



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning & Operation of Ganscoater (GAC-1500)	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 Ganscoater.

2.0 SCOPE:

2.1 This SOP is applicable for the cleaning and operation of Ganscoater and its accessories in the production area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation
3.2 Production Officer/ Executive : Checking Cleaning and Operation
3.3 IPQA Person : Line Clearance, On line Process Confirmation.
3.4 Head Production : SOP Compliance

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 Remove and destroy "TO BE CLEANED" label and Affix "UNDER CLEANING" label.
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 Dedust the external surface of Ganscoater, solution tank with clean lint free cloth.
5.1.4 Dedust the pan with lint free cloth.
5.1.5 Clean the pan with vacuum cleaner, if required.
5.1.6 Clean individual gun and spray nozzle with nylon bottlebrush.
5.1.7 Close the valve of solution feed vessel.
5.1.8 Remove the product inlet & outlet tubes from the nozzles of the solution feed vessel.
5.1.9 Dip these tubes into water.



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- 5.1.10 Remove the nozzles from the spray guns.
- 5.1.11 Reduce the atomizing air pressure to zero on HMI & hold a poly-bag in front of spray guns.
- 5.1.12 Run the peristaltic pump in high speed.
- 5.1.13 Continue this until fresh water comes out from spray guns and as well as from the return line.
- 5.1.14 Clean the solution supply pipe with lint free clean cloth. Clean solution supply pipe with water and 70% v/v IPA solution if required.
- 5.1.15 Clean the area as per SOP "Cleaning of Production Area".
- 5.1.16 Check and ensure that the equipment is visually clean.
- 5.1.17 Remove and destroy "UNDER CLEANING" label and Affix "CLEANED" status label duly filled and signed on the equipment.
- 5.1.18 Record the cleaning completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

NOTE

Ensure that spray guns & corresponding tubes cleaned to 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 / ascending potency / descending potency or after maintenance of contact parts.

- 5.2.1 Remove and destroy "TO BE CLEANED" label and Affix "UNDER CLEANING" label.
- 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 Cover the control panel, peristaltic pump, WIP pump and motor, air motor of solution tank and balance with poly bags to avoid water entry into them.
- 5.2.4 Ensure discharge of all coated tablets into collection bin prior to mobilize into washing mode.
- 5.2.5 Open the side panels and unbolt all baffles from the Pan inside.
- 5.2.6 Remove the gun arm outside by using the PLC. Ensure that there is no coating solution of the previous batch is left in the solution tank and the solution line.
- 5.2.7 Clean the inlet duct / outlet duct and accessible area of inlet duct / outlet duct line with jet of purified water.
- 5.2.8 Clean the inlet duct / outlet duct with nylon scrubber / wet lint free duster followed by dry lint free duster.
- 5.2.9 Cleaning to be done till the accessible area of inlet duct line / outlet duct line.



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- 5.2.10 Clean the inlet duct line and outlet duct line from outside by using wet lint free duster / wet nylon scrubber followed by dry lint free duster. Insert the gun arm inside the coating pan and close the side doors.
- 5.2.11 Fill the solution tank with 30-40 liter of purified water.
- 5.2.11.1 Reduce the atomizing air pressure to zero on HMI.
- 5.2.11.2 Run the pan at 2 rpm and peristaltic pump at high speed.
- 5.2.11.3 Stop the pan and peristaltic pump.
- 5.2.12 The sink provided at the bottom of the pan shall be filled with water. Rotating the drum through water contained in the sink shall clean the pan.
- 5.2.13 Follow the instruction given in MMI Parameter and start the cleaning.
- 5.2.13.1 **In case of coating solution contains enteric coating polymer/ methacrylic acid:** Repeat the step 5.2.12 and 5.2.13 with sink filled by 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.12 and 5.2.13 with purified water.
- 5.2.14 By selecting the no. of cycle for cleaning system will start again cleaning after end of one cycle.
- 5.2.15 Whole cleaning procedure will be repeated again and again as the no. of cycle is feeded.
- 5.2.16 Cleaning done in manual mode as screen display as WIP following data appear.
- 5.2.17 Select WIP Display WIP Parameter.
- 5.2.18 **1-WIP Rinse Cycle**

	Set Va.	P.Va
PAN RPM-	---	
FILLING TIME	--- Secs	--- Secs
WASHING TIME-	--- Secs	--- Secs
NO. OF RINSE CYCLE	---	

5.2.19 **2-Air Purging Time**

	Set Va.	P.Va
PAN RPM	---	
Air Purging Time	--- Secs	--- Secs



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5.2.20 3-WIP Drying Cycle

PAN RPM	---
INLET TEMP.	---°C
EXHAUST TEMP.	---°C
INLET BLOWER RPM	---
EXHUAST BLOWER RPM	---
DRYING TIME	--- Secs

Back Next

5.2.21 Select Next WIP RUN Screen will display As-

WIP Start	WIP Stop	Parameter	Retractable Arm In	Retractable Arm Out	Holding tank
-----------	----------	-----------	--------------------	---------------------	--------------

5.2.22 In WIP cycle enter the following parameters in rinse cycle Pan rpm = 2.0 rpm, filling time = 300 secs, washing time = 60 secs, draining time = 120 secs and no of WIP rinse cycles = 08. In air purging cycle enter pan rpm = 2.0 rpm and air purging time = 300 secs. In WIP drying cycle enter pan rpm = 2.0 rpm, inlet temp = 65°C, exhaust temp = 40°C, Inlet Blower rpm = 2000 rpm, exhaust blower rpm = 1400 rpm and drying time = 1800 secs

5.2.23 Open the valve of purified water and press “WIP START” key on the PLC to start “WIP RINSE CYCLE”.

5.2.24 After completion of the “WIP RINSE CYCLE” stop the WIP by pressing “WIP STOP” key on the PLC.

5.2.25 Remove the gun arm outside by using the PLC and open the side doors. Logout and switch OFF the machine using toggle switch.

5.2.26 Clean the cabinet surrounding the coating pan from inside, outside and top by using nylon scrubber and wet lint free duster followed by dry lint free duster.

5.2.27 Scrub the pan with nylon brush to soften the adhered matters and re-clean with fresh purified water if necessary.

5.2.27.1 **In case of coating solution contains enteric coating polymer/ methacrylic acid:** Repeat the step 5.2.27 with 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.27 with purified water.

5.2.28 Remove the silicone pipe from peristaltic pump used for coating solution transfer along with the connector and clean with purified water. Clean the peristaltic pump and its cover with wet lint free duster followed by dry lint free duster.



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- 5.2.29 Ensure that no coating residue present inside and outside of the solution pipe.
- 5.2.30 Dry the pipe using compressed air.
- 5.2.31 Transfer the pipe to washing area, and hang the pipe in inverted position so as to allow complete drain of water.
- 5.2.32 Dismantle the coating solution spray guns from the solution line. Open and wash the ring, cap nozzles and needle of the gun with 5-10 liters of purified water using nylon brush.
- 5.2.33 Clean the coating solution spray guns and compressed air tubes by using wet lint free duster and nylon scrubber followed by dry lint free duster / compressed air. Cleaning to be verified visually.
- 5.2.34 Clean the SS solution line of gun arm from outside and inside using nylon scrubber brush from both ends and jet of purified water.
- 5.2.35 Clean the gun arm and acrylic door with wet lint free duster followed by dry lint free duster. Switch ON the machine using toggle switch insert the gun arm inside the pan.
- 5.2.36 Press the “WIP” key on the PLC and start the “WIP RINSE CYCLE” followed by “AIR PURGING CYCLE” and “WIP DRYING CYCLE”
- 5.2.37 Clean all the baffles along with its Teflon sheet with jet of 25-30 liters by using nylon scrubber and finally rinse with 5-10 liters of purified water. Dry using dry lint free duster / compressed air.
- 5.2.38 Open the acrylic cover of discharge hood and clean the discharge hood along with its acrylic cover with wet lint free duster and nylon scrubber. Dry the discharge hood and acrylic cover of discharge hood by using compressed air and cleaned dry lint free duster and ensure the complete removal of water. Fix the acrylic cover at its place.
- 5.2.39 Clean the discharge chute with the help of wet lint free duster followed by dry lint free duster.
- 5.2.40 Open the lower side guards below the side doors and clean with nylon scrubber / wet lint free duster and dry using dry lint free duster / compressed air.
- 5.2.41 Clean the accessible area beneath the coating pan with wet nylon scrubber / wet lint free duster followed by dry lint free duster.
- 5.2.42 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).
- 5.2.43 Clean the cleaned parts with 0.4% before final rinsing of equipment/ parts in case of coating solution contains enteric coating polymer/ methacrylic acid.



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- 5.2.44 Drain the Purified water from the sink by opening valve at rear of Main pain Unit. And confirm complete draining of water.
- 5.2.45 Finally Rinse the cleaned parts with 40-60 liters of purified water.
- 5.2.46 Remove the water droplets from the equipment with help of compressed air if necessary.
- 5.2.47 Wipe the inner surface of pan, outer surface of the body of coater with lint free duster dipped in 70 % v/v IPA.
- 5.2.48 Dedust the control panel, peristaltic pump, and WIP pump with clean lint free cloth
- 5.2.49 Re-assemble the baffles, plenums, side panels and guns.
- 5.2.50 Clean the area as per SOP “Cleaning of Production Area”.
- 5.2.51 Ensure that the equipment is visually clean.
- 5.2.52 Remove and destroyed “UNDER CLEANING” label and Affix ‘CLEANED’ label on the equipment, duly filled and signed by production and QA personnel.
- 5.2.53 If the equipment remains idle for more than 72 hours after cleaning, then clean the equipment by wiping with 70% v/v IPA solution before use.
- 5.2.54 Record the cleaning observations in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

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.

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”. If the machine has been idle for 240 hrs/ 10 days or more after type B cleaning, then re clean the equipment by following the type B cleaning prior to use.

5.4 Machine Setting



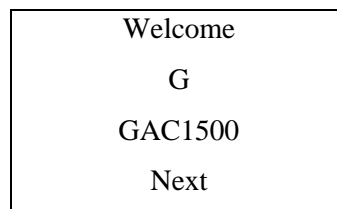
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- 5.4.1 Ensure that the equipment and area is cleaned. Remove and paste “CLEANED” label in the respective BMR. Affix “EQUIPMENT STATUS” label duly filled and signed on the equipment and record it in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.4.2 Ensure that the compressed air and main electric supply is ‘ON’ from service area.
- 5.4.3 Ensure that Compressed air pressure on pressure gauge is approximately 6 Mpa and more up to 10 Mpa.
- 5.4.4 Set the all spray guns on the retractable arm.
- 5.4.5 Set the silicon tubes with the peristaltic pump, retractable arm, and with the spray guns. Connect the return line tubes with the retractable arm at one end and with the holding tank at the other end.
- 5.4.6 Open the side covers to check the cleanliness of inlet and exhaust plenums. Attached the inlet and exhaust plenum to the machine. And bolt the plenum cover.
- 5.4.7 Turn the power ‘ON/OFF’ key to ‘OFF’ position. MMI will turn OFF.
- 5.4.8 Turn Control ‘ON/OFF’ switch on control panel to ‘ON’ position. Opening screen will open on MMI.
- 5.4.9 Welcome screen will display as



- 5.4.10 Touch the screen Next the main menu will appear with content as
- | | |
|-------------|--------------|
| Auto Mode | System |
| Manual Mode | Plant Layout |
| Reset | Trend Graph |
| Log In | Log Out |
| Back | |



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5.4.11 Select Log in it display as-

Name	
Password	
Current User: A/B/C	
Home	Return Log in

Current User- A- for operator

B-for supervisor

C-for Manager level

5.4.12 A level is only for operation and In level B recipe can be added

NOTE

- * Retractable arm assembly and necessary angle adjustment to the header is possible, such as to adjust Height- wise, Horizontal axis – wise and Angular- wise (0-90 degree) so that the distance from the tablet-bed maintained.
- * Check that the Teflon screwed with inlet and exhaust plenum of pan and plenum fitted to the pan properly.
- * During running of the coating machine the return line pipe shall carry excess coating material to the holding tank for accumulation.

5.5 AUTO MODE SETTING:

5.5.1 Create Recipe:

5.5.2 Chose current user B and feed there password and log in then touch Return

5.5.3 Select **Auto Mode** MMI show Check list. To move the screen forward and backward, touch the BACK on the screen for backward and NEXT for the forward.

5.5.4 Pre-Check list-

1-Check Atomization Air Pressure kg/cm.sq. (6-10)

2-Check Spray Pattern

3-Check Bed To Gun Distance cm

4-Check Spray Rate gms/min

5-Check Pan Depression mwWc

6-Confirm Program set Parameters

7-Check and record the wt. Of Core after pre jog cycle

Back

Next



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5.5.5 Select Next screen will display-

Mode Selection

Film

Parameters

Recipes

5.5.6 To feed parameter select parameter option then display show the following which to feeded as per Batch record for the coating operation-

Product Name ---

Product Code ---

Inlet Blower RPM ---

Exhaust Blower RPM ---

Print Interval --- min

Back

Next

5.5.7 Select Next screen will display as-

Pre Jog Cycle system

Pan RPM ----

Pan on time ---- Secs

Pan off time ---- Secs

Pan cycle ----

Pre Jog Inlet Temp. ----°C

Pre Jog Exhaust Temp. ----°C

Back

Next



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5.5.8 Select Next display show- **DOSING CYCLE SECTION**

CYCLE

Dosing Cycle Step 1

Pan RPM ----
Dosing RPM ----
Dosing On Time ---- Sec
Dosing Off Time ---- Sec
Dosing cycle ----
Film cycle inlet time ----°C
Film cycle Exhaust time ----°C

Back

Next

There is five time of Dosing Cycle stepwise. With same data.

If the coating is not proper then go for next cycle by adding data to get proper coating.

Otherwise next steps could not be selected.

Here coating is completed.

Note: Now go for post coating operation-

5.5.9 **Post Jog Cycle System**

Pan RPM ----
Pan On Time ---- Sec
Pan Off Time ---- Sec
Pan Cycle ----
Post jog Inlet temp. ----°C
Post jog Exhaust temp ----°C

Back

Next

This cycle system intended for drying after coating.



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5.5.10 Select next the tolerance value screen will display as-

Inlet temp + ve tolerance. ----°C

Exhaust temp + ve tolerance. ----°C

Exhaust temp – ve tolerance. ----°C

Holding Tank Agitator on time. ---- Sec

Holding Tank Agitator off time ---- Sec

Pan Jam Fault Bypass NO

Back

Next

There is no negative tol. Value for inlet temp.

5.5.11 Select Next, screens go to the mode selection-running screen. As-

Mode Selection

Film

Parameter

Recipes

5.5.12 Select Recipe

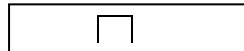
5.5.13 **Recipe:** Display as –

Recipe

Make Recipe

Select Recipe

5.5.14 In select Recipe there is two option as



Load

View Recipe

In this write recipe name and load the recipe and in view Recipe the detail of batch will show.

5.5.15 In Make recipe:

Create new

Save

Delete

Load



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5.5.16 As select create new System generate r2 or r3---r---, to this system generated name change by the product name by touching in the same space. Now Save, the system ask Are you sure to save recipe? And provide two options Yes or No then touch yes the recipe get save. Now select Load the prepared recipe will be loaded in the system.

5.5.17 This new recipe can be use by option **select recipe** it show Load and view recipe option, then chose recipe and load it.

5.5.18 After Loading the recipe go on back option screen will display as

Mode Selection

Film

Parameter
Recipe

Back
Next

5.5.19 Select Next window display Batch Details as-

Product Name

 Product Coed

Batch Code

Lot No

Back
Next

5.5.20 Here product name and product coed take automatically as the recipe was selected and batch code and lot No can be change by selecting blocks. Now select Next the run screen will be display

Auto Film Mode

Print	End Process	Retractable arme in	Retractable arme out	Holding Tank	Pause Dosing	Pause Process	Start/count
-------	-------------	---------------------	----------------------	--------------	--------------	---------------	-------------

5.5.21 The above provided boxes are fore the operation to be started or to stop.



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5.6 MANUAL MODE

5.6.1 Select manual mode, screen will display as- Manual Mode Selection.

Mode Selection

Film

Parameters

Select Manual Mode

5.6.2 By selecting Parameter screen show the parameter to be feeded as per batch record.

Inlet Blower RPM -----

Exhaust Blower RPM -----

Pan RPM -----

Dosing RPM Forward/ Reverse -----

Inlet Temp. ----°C

Exhaust Temp. ----°C

Back

Next

5.6.3 Select Next it show Tolerance value as-

Exhaust Temp +ve Tol. -----°C

Exhaust Temp – ve Tol. -----°C

Inlet Temp +ve Tol. -----°C

Print Interval ----mins

Holding Tank Ag. On time ----Secs

Holding Tank Ag. Off time ----Secs

Pan Jam Fault Bypass No

Back

5.6.4 Select Back screen will display as- Manual Mode Selection.

Mode Selection

Film

Parameter

Select Manual Mode

Back

Next

5.6.5 Now the parameter for manual mode feeded then touch the Select Manual Mode then Manual Mode selection run screen will display and then start the operation by commanding as the screen display-



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Retractable arme in	Retractable arme out	Holding Tank	Scrubber	Dosing	Inlet	Exhaust	Pan
------------------------	-------------------------	-----------------	----------	--------	-------	---------	-----

On the top of the screen displays Min menu, Trends, Plant Layout, System, Parameters, Gun Validation and WIP blocks. By selecting Trends, screen displays Inlet Temp. Ex. Temp. , And Bed Temp. Trends by selecting the respective one.

5.6.6 Displays shows the all the parameters like inlet temperature, exhaust temperature, bed temperature, Pan RPM, Inlet blower, Exhaust blower, Solution weight and Spray rate of coating solution.

5.6.7 **TABLET DISCHARGE:**

5.6.7.1 Remove the retractable arm out.

5.6.7.2 Swing back the arm on right hand side and lock it.

5.6.7.3 Fit the scoop shovel in between the set of baffles, automatically plate fits into the mouth, it is to be locked by handle, check holding block resets on to the rim of the pan firmly.

5.6.7.4 Top cover to be put on to the mouth opening.

5.6.7.5 Loosen the two knobs, so that cover brackets can fit easily. Then tighten the knobs.

5.6.7.6 Start the pan in Reverse direction. On every rotation scooping is affected.

5.6.7.7 After complete discharge of the tablets, remove the cover, remove the scoop.

5.6.7.8 Now the machine is ready for washing / cleaning for the next batch.

6.0 **ABBREVIATION (S):**

6.1 IPA : Iso Propyl Alcohol

6.2 SOP : Standard Operating Procedure

6.3 v/v : Volume/Volume

6.4 ml : Milliliter

6.5 BMR : Batch Manufacturing Record

6.6 MMI : Man Machine Interface

6.7 Mpa : Mili Pascal

6.8 WIP : Wash In Place

6.9 RPM : Round Per Minute

6.10 NAOH : Sodium hydroxide



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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.

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of execution
Annexure-I	Cleaning checklist of Ganscoater (gac-1500).		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (s)** : Production department (01), Quality Assurance (01)
- 9.3 **Reference copy (s)** : Production department (03)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details Of Revision	Effective Date
01	00	NA	New SOP	NA	NA



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ANNEXURE I

CLEANING CHECKLIST OF GANSCOATER (GAC-1500)

Equipment Name	Ganscoater (GAC-1500)	Date	
Equipment ID		Area	
Previous Product		Batch No.	
S.No.	Check Points		Activity performed
1.	Cover the control panel, peristaltic pump, WIP pump and motor, air motor of solution tank and balance with poly bags to avoid water entry into them.		
2.	Ensure discharge of all coated tablets into collection bin prior to mobilize into washing mode.		
3.	Open the side panels and unbolt all baffles from the Pan inside.		
4.	The sink provided at the bottom of the pan shall be filled with water. Rotating the drum through water contained in the sink shall clean the pain.		
5.	In case of coating solution contains enteric coating polymer/ methacrylic acid: Repeat the step 5.2.6 and 5.2.7 with sink filled by 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.6 and 5.2.7 with purified water.		
6.	Follow the instruction given in MMI Parameter and start the cleaning.		
7.	By selecting the no. of cycle for cleaning system will start again cleaning after end of one cycle		
8.	Whole cleaning procedure will be repeated again and again as the no. of cycle is feeded.		
9.	Cleaning done in manual mode as screen display as WIP following data appear.		
10.	Select WIP Display WIP Parameter		
11.	Cleaning activity performed according to the WIP cleaning cycle, air purging time cycle, and WIP drying cycle.		
12.	The external surface including column, top cover, side panels etc. will be wiped with moist lint free duster dipped in purified water. Finally wipe with 70 % v/v IPA solution.		
13.	Cover the control panel, peristaltic pump, WIP pump and motor, air motor of solution tank and balance with poly bags to avoid water entry into them.		
14.	Ensure discharge of all coated tablets into collection bin prior to mobilize into washing		



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	mode.	
15.	Open the side panels and unbolt all baffles from the Pan inside.	
16.	The sink provided at the bottom of the pan shall be filled with water. Rotating the drum through water contained in the sink shall clean the pain.	
17.	Follow the instruction given in MMI Parameter and start the cleaning.	
18.	By selecting the no of cycle for cleaning system will start again cleaning after end of one cycle.	
19.	Whole cleaning procedure will be repeated again and again as the no of cycle is feeded.	
20.	Cleaning done in manual mode as screen display as WIP following data appear.	
21.	The Baffles, Gun, Dosing rake, Plenums, Solution holding tank and peripherals to be take it to the washing areas for appropriate cleaning and finally wipe with 70 % v/v IPA solution	
22.	Close the valve of solution feed vessel.	
23.	Remove the product inlet & outlet tubes from the nozzles of the Solution feed vessel.	
24.	Dip these tubes into purified water.	
25.	Remove the nozzles from the spray guns.	
26.	Reduce the atomizing air pressure to zero on HMI & hold a poly-bag in front of spray guns.	
27.	Run the peristaltic pump in high speed. Continue this until fresh water comes out from spray guns and as well as from the return line.	
28.	Scrub the pan with nylon brush to soften the adhered matters and re-clean with fresh purified water if necessary.	
29.	In case of coating solution contains enteric coating polymer/ methacrylic acid: Repeat the step 5.2.19 with 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.19 with purified water.	
30.	Drain the water from the sink by opening valve at rear of Main pain Unit. And confirm complete draining of water.	
31.	Remove the water droplets from the equipment with help of compressed air if necessary.	
32.	Finally Rinse the cleaned parts with 40-60 liters of purified water.	
33.	Wipe the inner surface of pan, outer surface of the body of coater with lint free duster dipped in 70 % v/v IPA.	
34.	The Baffles, Gun, Dosing rake, Plenums, Solution holding tank and peripherals to be	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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	take it to the washing areas for appropriate cleaning and finally wipe with 70 % v/v IPA solution	
35.	Dedust the control panel, peristaltic pump, and WIP pump with clean lint free cloth.	
36.	Re-assemble the baffles, plenums, side panels and guns.	
37.	Remove and destroy the "UNDER CLEANING" label Affix 'CLEANED' label on the equipment, duly filled and signed by production and QA personnel.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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