STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Multi Pan Coater	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Multi pan Coater (Make: Ganscoater GAC-900/600).

2.0 SCOPE:

This SOP applies to the Cleaning and Operation of Multi pan Coater (Make: Ganscoater GAC-900/600) in Production area.

3.0 RESPONSIBILITY:

Technical Associate	: Cleaning and Operation
Officer and Executive	: Supervision
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 changeover from one batch to next batch of the same product, same potency.

5.1.1 Remove and destroy "TO BE CLEANED" label.

5.1.2 Enter the cleaning starting 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 bottle brush.

5.1.7 Close the valve of solution feed vessel

5.1.8 Remove the product inlet tubes from the nozzles of the solution feed vessel.

5.1.9 Dip these tubes into water.

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.

5.1.15 Clean solution supply pipe with water and 70% v/v IPA solution if required.

5.1.16 Clean the area as per SOP (Cleaning of Production area).

5.1.17 Check and ensure that the equipment is visually clean.

5.1.18 Affix "CLEANED" status label duly filled and signed on the equipment.

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

5.1.20 **NOTE:** Check the integrity of silicon tube and ensure that spray guns & corresponding tubes is cleaned .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.

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 plenum and unbolt all baffles from the pan inside.

5.2.6 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.

5.2.7 Follow the instruction given in MMI Parameter and start the cleaning.

5.2.8 By selecting the number of cycle for cleaning, cleaning cycle shall start, after end on cycle next cycle shall start.

5.2.9 Whole cleaning procedure will be repeated again and again as per the no. of cycle.

5.2.10 Select WIP Display WIP Parameter.

5.2.11 **WIP System:**

5.2.11.1 By pressing start Water cycle, Air purge cycle and Drying & Cooling cycle takes place.

5.2.11.2 **Water cycle:** By pressing start inlet valve SV-7 will get open and WIP pump will start to fill water into the PAN for set WIP fill time. As WIP fill time gets over inlet valve will get close and Pan Motor will start for set WIP on time.

5.2.11.3 As WIP time gets over drain valve SV-8 will open for a set time and get closed when drain time complete.

5.2.11.4 **Air Purge Cycle:** During this cycle inlet valve have to keep close.

5.2.11.5 When cycle starts air purging valve SV-10 and WIP drain valve SV-8 will open and pan run at set RPM. When time over both valve close.

5.2.11.6 **Drying & Cooling Cycle:** System checks for the exhaust temperature. Once the exhaust temperature is reached the drying cycle start.

5.2.11.7 After completion of all the cycles in WIP alarm triggered as 'WIP Cycle Over'.

5.2.12 The external surface including column, top cover, side plenum etc will be wiped with moist lint free duster dipped in purified water. Finally wipe with 70 % v/v IPA solution.

5.2.13 Finally wipe the Baffles, Gun, Dosing rake, Plenums, Solution holding tank and peripherals with 70 % v/v IPA solution.

5.2.14 **Method of cleaning for spray guns and corresponding silicon tubes:**

5.2.14.1 Close the valve of solution feed vessel.

5.2.14.2 Remove the product inlet & outlet tubes from the nozzles of the Solution feed vessel.

5.2.14.3 Dip these tubes into purified water.

5.2.14.4 Remove the nozzles from the spray guns.

5.2.14.5 Reduce the atomizing air pressure to zero on HMI & hold a poly-bag in front of spray guns.

5.2.14.6 Run the peristaltic pump in high speed.

5.2.14.7 Flush 20-25 liters of purified water from solution pipes. If any adhere material observed inside the solution pipes use 70% v/v IPA for flushing (If required).

5.2.15 Scrub the pan with nylon brush using 20-25 liters of purified water to soften the adhered matters and re-clean with fresh 10-15 liters of purified water if necessary.

5.2.16 Drain the water from the sink by opening valve at rear of main pan unit. Confirm complete draining of water.

5.2.17 Finally Rinse the cleaned parts with 90-100 liters of purified water.

5.2.18 Clean the cleaned part with 0.4% sodium hydroxide solution (for 1 litre 0.4% sodium hydroxide, take 4 g sodium hydroxide and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case enteric coating of tablets. Rinse the coating pan dipped with 0.4% sodium hydroxide solution.

5.2.19 Remove the water droplets from the equipment with help of compressed air if necessary.

5.2.20 Wipe the inner surface of pan, outer surface of the body of coater with lint free duster dipped in 70 % v/v IPA.

5.2.21 Deduct the control panel, peristaltic pump, and WIP pump with clean lint free cloth.

5.2.22 Re-assemble the baffles, plenums, side panels and guns.

5.2.23 Clean the area as per SOP (Cleaning of Production area).

5.2.24 Ensure that the equipment is visually clean.

5.2.25 Affix 'CLEANED' label on the equipment, duly filled and signed by production and QA personnel.

5.2.26 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.

5.2.27 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 change over of product with different actives/color/ ascending/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:

5.3.3 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).

Precautions:

1) Ensure the complete removal of water from gun assembly and air manifold by purging air into the connectors and assembly.
2) Ensure the peristaltic pump and dosing pipes are completely dry.

5.4 Machine Setting:

5.4.1 Ensure that the equipment and area is cleaned. Remove and paste "CLEANED" label in the respective BMR. Affix "UNDER PROCESS" label duly filled and signed on the equipment.

5.4.2 Assemble the desire coating pan as per mentioned in BMR.

5.4.2.1 Unscrew the inlet and outlet duct, open the door 2 of auto coater, align the trolley with wheel of pan holder cage and pull the pan to remove existing pan.

5.4.2.2 Attached cleaned label, shrink wrapped and transfer to cleaned room.

5.4.2.3 Desire size pan is assembled and fit the inlet, outlet duct.

5.4.2.4 Check the cleanliness of pan before assemble.

5.4.3 Ensure that the compressed air and main electric supply is 'ON' from service area.

5.4.4 Ensure that Compressed air pressure on pressure gauge is approximately 5 kg/cm^2.

5.4.5 Set the all spray guns on the retractable arm.

5.4.6 Visually check the integrity of silicon tube and set the silicon tubes with the peristaltic pump, retractable arm, and with the spray guns.

5.4.7 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.

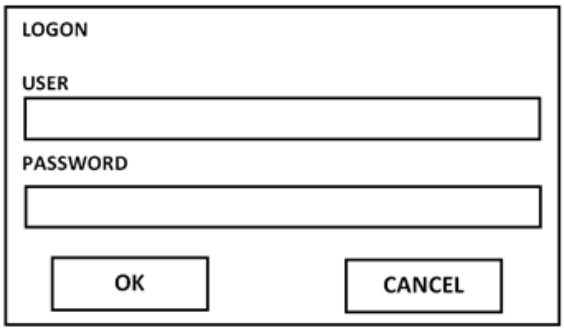
5.4.8 Retractable arm assembly and necessary angle adjustment to the header is possible, such as to adjust Height- wise, Horizontal axis – wise and Angular- wise (0-90 degree) so that the distance from the tablet-bed maintained.

5.4.9 Check that the Teflon screwed with inlet and exhaust plenum of pan and plenum fitted to the pan properly.

5.4.10 Turn the power 'ON/OFF' key to 'ON' position. MMI will turn ON.

5.4.11 Touch the "⇨" on the main screen to open the login screen.

5.4.12 Select Log in it display as:



5.4.13 After filling User and Password, touch the 'ENTER' on the key board display on the screen.

5.4.14 Login done. For next screen again touch the '⇨' mark on the main screen.

5.4.15 The main screen shown as below:

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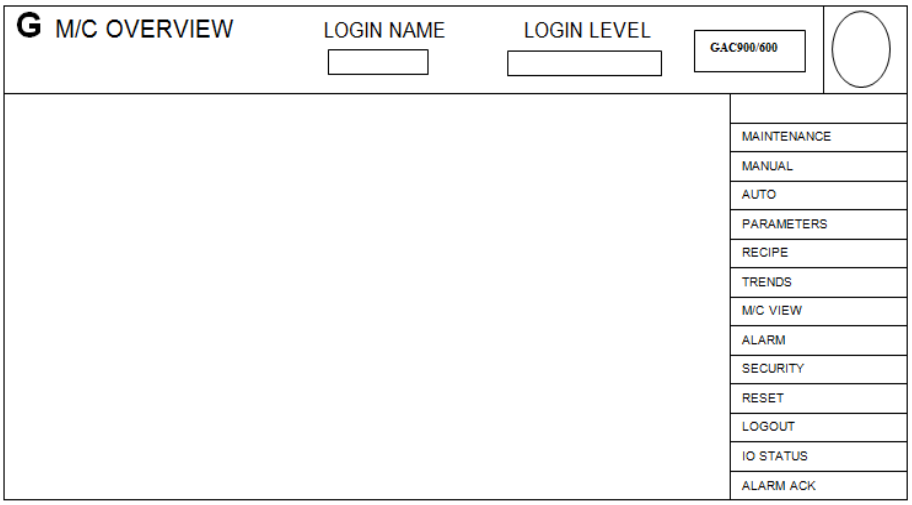


5.4.16 Current Levels-

A- for Operator : Machine Operation

B-for Supervisor : Recipe Load

C-for Manager : Recipe Load and Edit

D-for Maintenance : For machine maintenance

5.4.17 For the selection of one to other mode like manual to auto mode, press the 'RESET'. Pop up will display on the screen. In the screen message will display 'Are you sure to RESET' then press 'YES' or 'NO' button as required.

5.5 Make/ Edit and Delete Recipe Parameters:

5.5.1 On pressing 'PARAMETERS' in the 'RECIPE MGMT.' column select the 'Make/ Select'.

5.5.2 Enter the recipe name at the 'Data Record Name' with the help of keys. Recipe No. shown at subsequent block.

5.5.3 Enter the recipe details of 'Enter Name' column by selecting 'Value' column with the help of keys.

5.5.4 **The parameters to be entered are listed below:**

Product Name Product Code

Batch No. Lot No.

5.5.5 Next by pressing the down word parameters shows as:

Inlet Air Temperature Max +ve Tol.:

Inlet Air Temperature Max -ve Tol.:

Exhaust Air Temperature +ve Tol.:

Exhaust Air Temperature -ve Tol.:

Solution Agitator OFF Time:

Solution Agitator ON Time:

5.5.6 Press Next and following screen appears:

HEPA filter DP High High:

HEPA filter DP High:

HEPA filter DP Low:

Condensation on Time:

Process Control By:

5.5.7 Press next screen:

Print interval:

Process Selection:

Pan DP PID:

Inlet Air Temperature: Exhaust Air Temperature:

Inlet Blower RPM: Exhaust Blower RPM:

Pan Speed: Pan Motor on Time:

Pan Motor Off Time: No of Cycle:

5.5.8 Press next screen: (STEP-1 Parameters)

Inlet Air Temperature: Exhaust Air Temperature:

Inlet Blower RPM: Exhaust Blower RPM:

Pan Motor Speed: Dosing Pump Speed:

Dosing Motor on Time: Dosing Motor Off Time:

No of Cycle:

5.5.9 Press next screen: (STEP-2 Parameters)

Inlet Air Temperature: Exhaust Air Temperature:

Inlet Blower RPM: Exhaust Blower RPM:

Pan Motor Speed: Dosing Pump Speed:

Dosing Motor on Time: Dosing Motor Off Time:

No of Cycle:

5.5.10 Same screen appears with STEP-1, STEP-2…….up to SETP-5, fill the required parameters as per product BMR.

5.5.11 Press Next Screen (Post Jog Parameters):

Inlet Air Temperature: Exhaust Air Temperature:

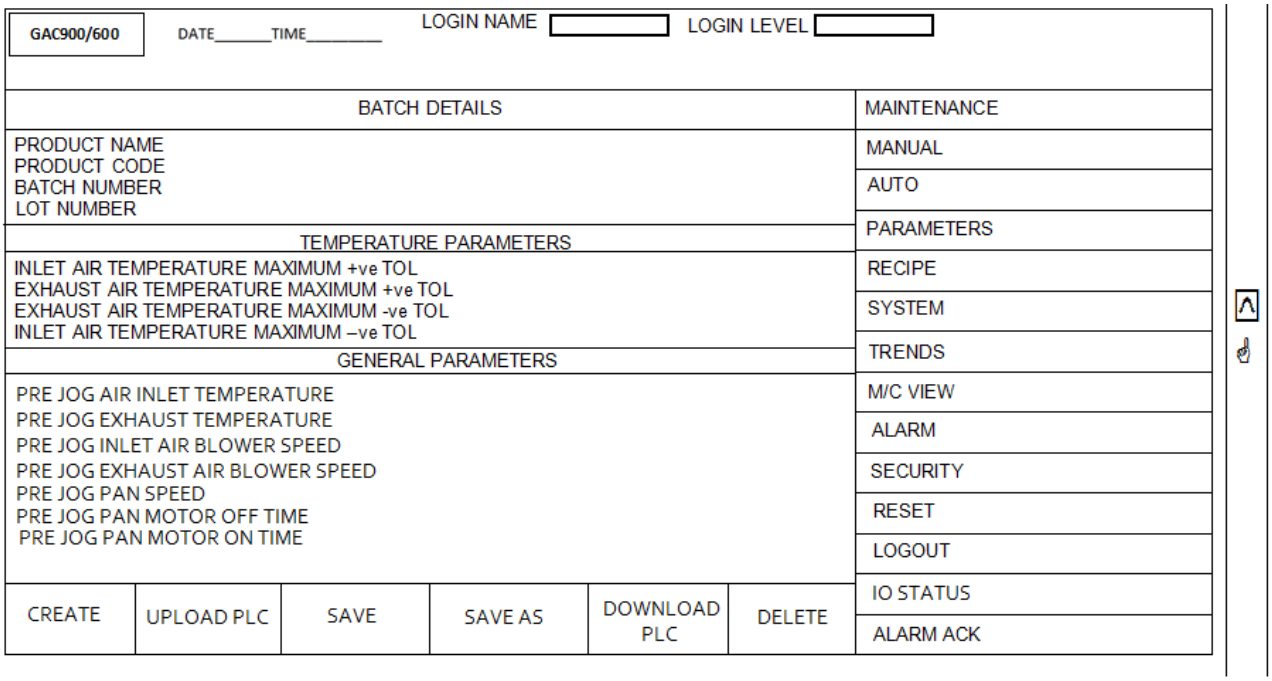
Inlet Blower RPM: Exhaust Blower RPM:

Pan Motor Speed:

Pan Motor on Time: Pan Motor off Time

Number of Cycles:

5.5.12 After filling parameters as per BMR, press 'RECIPE KEY' then following screen appears:



5.5.13 Update the parameters as per Product BMR and press 'UPLOAD PLC' and the 'SAVE AS'.

5.5.14 Now press the 'DOWNLOAD PLC' to load the recipe parameters to execute the process.

5.5.15 Batch enters parameters to be shown on 'PARAMETERS' mode.

5.5.16 By sliding through the corner of the PLC screen we check and correct the 'PRE JOG PARAMETERS', 'STEP 1 PARAMETERS', 'STEP 2 PARAMETERS', 'STEP 3 PARAMETERS', 'STEP 4 PARAMETERS', 'STEP 5 PARAMETERS', and 'POST JOG PARAMETERS'

5.5.17 For delete recipe, press 'DELETE' red mark.

5.5.18 Massage shown as:

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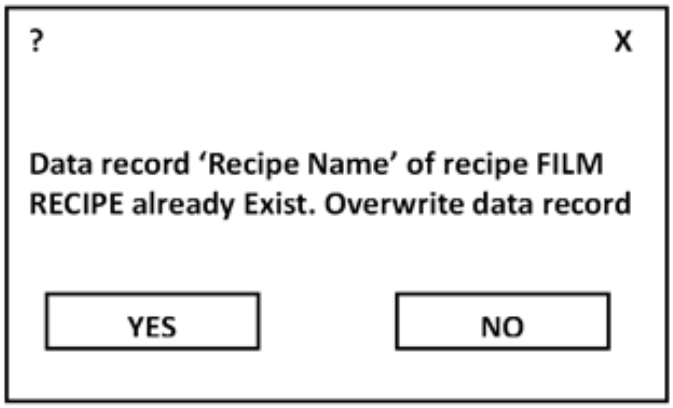

5.6 Manual Mode Operation

5.6.1 To start the machine in 'MANUAL MODE' select the manual mode from the main screen, at the manual mode screen we edit the 'TEMPERATURE PARAMETERS', gun validation and WIP.

5.6.2 Temperature parameters and all the other relevant parameters to be edit as per given the respective BMR.

5.6.3 By pressing 'NEXT' on the screen main Manual mode screen shows. Here Arm IN, Arm Out, Pan, Exhaust, Inlet, Dosing, WIP, Gun Validation.

5.6.4 Press 'NEXT' for Solution Agitator OFF TIME/ON TIME, PAN JOG FAULT, CONDENSATION ON TIME, PAN DP PID.

5.6.5 Press 'NEXT' for PAN MOTOR SPEED, DOSING PUMP SPEED, DOSING ON TIME, DOSING OFF TIME, INLET BLOWER, OUTLET BLOWER.

5.6.6 Press 'NEXT' for PROCESS CONTROL, HEPA FILTER DP HIGH HIGH, HEPA FILTER DP HIGH and HEPA FILTER DP LOW.

Note: When inlet & exhaust blower on, inlet & exhaust damper will open

5.6.7 Load the tablet in the Auto Coater. Start the inlet and exhaust blower and the inch the pan intermittently to preheat the tablet as given in the respective BMR.

5.6.8 After preheating press the 'DOSING' on the main screen. On clicking Atomizing on first then after 15 sec Needle output will on and after that Dosing pump will start on respectively with intervals of 2 seconds.

5.6.9 After completion of coating process press the 'DOSING' again. Dosing stops.

5.6.10 After drying and cooling of coated tablets unload the batch from the pan as 5.8.

5.7 Auto mode Operation:

5.7.1 To start the machine in 'AUTO MODE' selects the Auto Mode from the main screen.

5.7.2 Select the recipe from the DATA RECORD on screen for the desired product recipe and press DOWNLOAD PLC key

5.7.3 On selecting 'FILM' after the parameters screen 'AUTO-FILM MODE' run screen will display.

5.7.4 After checking all the interlocks, press 'START' to start the machine in Auto Mode.

5.7.5 By pressing 'START' sequentially turning ON the scrubber followed by exhaust blower after the water pressure is reached.

5.7.6 Once the exhaust blower ON, Inlet blower will ON after 15 seconds.

5.7.7 When the Exhaust temperature reaches to the set exhaust temperature the Pre Jog cycle will start.

5.7.8 Here inlet temperature controlled by PID.

5.7.9 After completion of pre jog cycle, system checks for the exhaust temperature before starting the dosing cycle. Once the temperature reaches the pan motor will be ON and delay of 3 seconds Dosing cycle will start.

5.7.10 After completion of Dosing cycle as set in Dosing step 1,2,3,4,5, over Dosing cycle will over.

5.7.11 After completion of Dosing cycle Post Jog cycle starts when the exhaust temperature reaches to set temperature the Post Jog cycle will start.

5.7.12 After completion of Post Jog cycle, pan motor turns off immediately followed by the inlet blower after delay of 2 seconds followed by the exhaust blower after a delay of 10 seconds and then scrubber at the end.

5.8 TABLET DISCHARGE:

5.8.1 Remove the retractable arm out.

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

5.8.3 Fit the discharge chute 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.

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

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

5.8.6 Start the pan. On every rotation scooping is affected. And tablets unloading started to product container.

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

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

6.0 ABBREVIATION (S):

IPA : Iso Propyl Alcohol

SOP : Standard Operating Procedure

v/v : Volume/Volume

ml : Milliliter
BMR : Batch Manufacturing Record
MMI : Man Machine Interface
Mpa : Mili Pascal
WIP : Wash In Place
RPM : Round per Minute
NaOH : Sodium Hydroxide

7.0 REFERENCE (S):

SOP: Making entries in Equipment Usage and Cleaning Log Sheet.
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-900/600)		Log Book
Annexure-2	Coating pan details		Log Book

9.0 DISTRIBUTION:

Master Copy : Quality Assurance
Controlled Copy (S) : Production Department (02), Quality Assurance(01)
Reference Copy (S) : Production Department (01)

10. REVISION HISTORY:

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

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ANNEXURE I

CLEANING CHECKLIST OF GANSCOATER (GAC-900/600)

Equipment Name	Ganscoater (GAC-900/600)		
Equipment ID		**Date**	
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 plenum and unbolt all baffles from the pan inside.	
4.	Select WIP Display WIP Parameter	
5.	Remove the product inlet & outlet tubes from the nozzles of the Solution feed vessel.	
6.	Dip these tubes into purified water.	
7.	Remove the nozzles from the spray guns.	
8.	Reduce the atomizing air pressure to zero on HMI & hold a poly-bag in front of spray guns.	
9.	Run the peristaltic pump in high speed.	
10.	Flush 20-25 liters of purified water from solution pipes. If any adhere material observed inside the solution pipes use 70% v/v IPA for flushing (If required).	
11.	Scrub the pan with nylon brush using 20-25 liters of purified water to soften the adhered matters and re-clean with fresh 10-15 liters of purified water if necessary.	
12.	Drain the water from the sink by opening valve at rear of main pan unit. Confirm complete draining of water.	
13.	Clean the cleaned part with 0.4% sodium hydroxide solution (for 1 liter 0.4% sodium hydroxide, take 4 g sodium hydroxide and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case enteric coating of tablets. Rinse the coating pan dipped with 0.4% sodium hydroxide solution.	(incase of enteric coating)
14.	Finally Rinse the cleaned parts with 90-100 liters of purified water.	
15.	Remove the water droplets from the equipment with help of compressed air if necessary.	
16.	Wipe the inner surface of pan, outer surface of the body of coater with lint free duster	

	dipped in 70 % v/v IPA.	
17.	Dedust the control panel, peristaltic pump, and WIP pump with clean lint free cloth.	
18.	Re-assemble the baffles, plenums, side panels and guns.	
19.	Clean the area as per SOP.	
20.	Ensure that the equipment is visually clean.	
21.	Ensure the complete removal of water from gun assembly and air manifold by purging air into the connectors and assembly.	
22.	Ensure the peristaltic pump and dosing pipes are completely dry.	
23.	Affix 'CLEANED' label on the equipment, duly filled and signed by production and QA personnel.	

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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ANNEXURE II

COATING PAN DETAILS

S.No.	Pan Size (Inch)	Pan Number	Perforation Size	Product Used For	Remarks