



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Ganscoater (GAC-1700)	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 purified 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.



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- 5.1.12 Run the peristaltic pump in high speed.
- 5.1.13 Continue this until fresh purified 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 purified 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 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 purified 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 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.
- 5.2.7 Follow the instruction given in MMI Parameter and start the cleaning.
- 5.2.8 **Method of cleaning in case of coating solution contains enteric coating polymer/ methacrylic acid:**
- 5.2.8.1 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.
- 5.2.9 By selecting the no. of cycle for cleaning system will start again cleaning after end of one cycle
- 5.2.10 Whole cleaning procedure will be repeated again and again as the no. of cycle is feeded.
- 5.2.11 Cleaning done in manual mode as screen display as WIP following data appear.



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5.2.12 Select WIP Display WIP Parameter.

5.2.13 **WIP System:**

5.2.13.1 By pressing start Purified water cycle, Air purge cycle and Drying & Cooling cycle takes place.

5.2.13.2 Purified water cycle: - by pressing start inlet valve SV-7 will get open and WIP pump will start to fill purified 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.

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

5.2.13.4 Air Purge Cycle: - during this cycle inlet valve have to keep close.

5.2.13.5 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.

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

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

5.2.14 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.

5.2.15 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.

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

5.2.16.1 Close the valve of solution feed vessel.

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

5.2.16.3 Dip these tubes into purified water.

5.2.16.4 Remove the nozzles from the spray guns.

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

5.2.16.6 Run the peristaltic pump in high speed.

5.2.16.7 Continue this until fresh purified water comes out from spray guns and as well as from the return line.

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

5.2.18 Drain the purified water from the sink by opening valve at rear of Main pain Unit. And confirm complete draining of purified water.

5.2.19 Finally Rinse the cleaned parts with 50-70 liters of purified water.



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- 5.2.19.1 In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step 5.2.19 with 50-70 litres 0.4 % NAOH solution and followed by with 50-70 litres purified water.
- 5.2.20 Remove the purified water droplets from the equipment with help of compressed air if necessary.
- 5.2.21 Wipe the inner surface of pan, outer surface of the body of coater with lint free duster dipped in 70 % v/v IPA.
- 5.2.22 Dedust the control panel, peristaltic pump, and WIP pump with clean lint free cloth
- 5.2.23 Re-assemble the baffles, plenums, side panels and guns.
- 5.2.24 Clean the area as per SOP "Cleaning of Production Area".
- 5.2.25 Ensure that the equipment is visually clean.
- 5.2.26 Affix 'CLEANED' label on the equipment, duly filled and signed by production and QA personnel.
- 5.2.27 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.
- 5.2.28 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 / 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: 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. Remove and paste "CLEANED" label in the respective BMR. Affix "Equipment status" label duly filled and signed on the equipment.
- 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 5 BAR.
- 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.



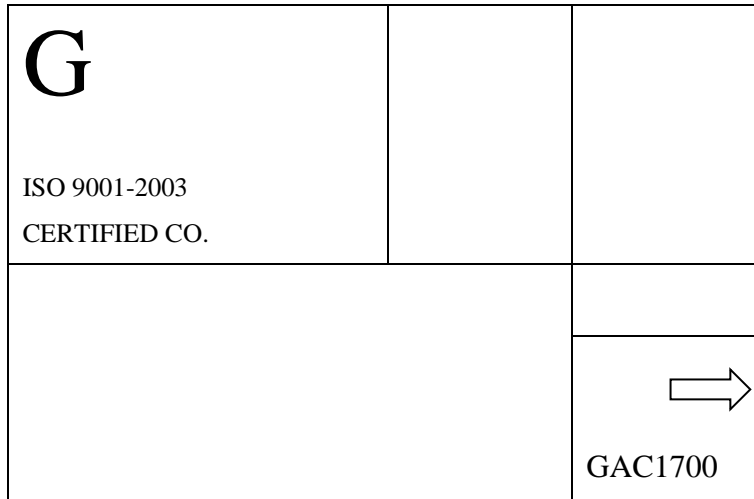
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
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- 5.4.6 Open the side covers to check the cleanliness of inlet and exhaust plenums. Attached the inlet and exhaust plenum to the machine. And bolt the plenum cover.
- 5.4.7 Retractable arm assembly 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.
- 5.4.8 Check that the Teflon screwed with inlet and exhaust plenum of pan and plenum fitted to the pan properly.
- 5.4.9 During running of the coating machine the return line pipe shall carry excess coating material to the holding tank for accumulation.
- 5.4.10 Turn the power ‘ON/OFF’ key to ‘OFF’ position. MMI will turn OFF.
- 5.4.11 Turn Control ‘ON/OFF’ switch on control panel to ‘ON’ position. Opening screen will open on MMI.
- 5.4.12 Welcome screen will display as



- 5.4.13 Touch the “  on the main screen to open the login screen.
- 5.4.14 Select Log in it display as-

LOGON	X
USER	<input type="text"/>
PASSWORD	<input type="text"/>
<input type="button" value="OK"/>	<input type="button" value="CANCEL"/>



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- 5.4.15 After filling User and Password, touch the 'ENTER' on the key board display on the screen.
- 5.4.16 Login done. For next screen again touch the '➡' mark on the main screen.
- 5.4.17 The main screen shown as below.

G		M/C OVERVIEW		
LOGIN NAME	<input type="text"/>	LOGIN LEVEL	<input type="text"/>	
			GAC1700	
				MODE
				MAINTENANCE
				MANUAL
				AUTO
				PARAMETERS
				RECIPE MGMT.
				MAKE/ SELECT
				SYSTEM
				TRENDS
				M/C OVERVIEW
				ALARM HISTORY
				SECURITY MGMT.
				RESET
				LOGOUT
				H/W DIAGNOSIS
				INPUTS-OUTPUTS
				DATE & TIME
				ALARM ACK

- 5.4.18 Current Levels- A- for operator
B-for supervisor
C-for Manager level
- 'A' level is only for operation and in level 'B' recipe can be added and in 'C' level editing, deleting existing recipe done.
- 5.4.19 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.



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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.

Inlet Air Temper Max pos Tol

Exhaust Air Temper Max neg Tol

Inlet Air Temper Max neg Tol

Pre Jog Inlet Air Temperature

Pre Jog Exhaust Air Temperature

Pre Jog Inlet blower Speed

Pre Jog Exhaust blower speed

Pre Jog Pan Motor Speed

Pre Jog Pan Off Time

Pre Jog Pan On Time

Pre Jog Cycles.



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5.5.5 Next by pressing the down word parameters shows as

- Film M Step 1 Exhaust Air Temperature
- Film M Step 1 Inlet Blower Speed
- Film M Step 1 Exhaust Blower Speed
- Film M Step 1 Pan Motor Speed
- Film M Step 1 Cycle Type Selection
- Film M Step 1 Dosing Off Time
- Film M Step 1 Dosing On Time
- Film M Step 1 Time
- Film M Step 1 Dosing Cycle
- Film M Step 1 Inlet Air Temperature
- Film M Step 2 Selection Yes No
- Film M Step 2 Inlet Air Temperature
- Film M Step 2 Exhaust Air Temperature
- Film M Step 2 Inlet Blower Speed
- Film M Step 2 Exhaust Blower Speed
- Film M Step 2 Pan Motor Speed
- Film M Step 2 Cycle Type Selection
- Film M Step 2 Dosing Off Time
- Film M Step 2 Dosing On Time
- Film M Step 2 Time
- Film M Step 2 Dosing Cycle



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Film M Step 3 Selection Yes No
Film M Step 3 Inlet Air Temperature
Film M Step 3 Exhaust Air Temperature
Film M Step 3 Inlet Blower Speed
Film M Step 3 Exhaust Blower Speed
Film M Step 3 Pan Motor Speed
Film M Step 3 Cycle Type Selection
Film M Step 3 Dosing Off Time
Film M Step 3 Dosing On Time
Film M Step 3 Time, Film M Step 3 Dosing Cycle
Film M Step 4 Selection Yes No
Film M Step 4 Inlet Air Temperature
Film M Step 4 Exhaust Air Temperature
Film M Step 4 Inlet Blower Speed
Film M Step 4 Exhaust Blower Speed
Film M Step 4 Pan Motor Speed
Film M Step 4 Cycle Type Selection
Film M Step 4 Dosing Off Time
Film M Step 4 Dosing On Time
Film M Step 4 Time
Film M Step 4 Dosing Cycle\
Film M Step 5 Selection Yes No
Film M Step 5 Inlet Air Temperature
Film M Step 5 Exhaust Air Temperature



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Film M Step 5 Inlet Blower Speed
Film M Step 5 Exhaust Blower Speed
Film M Step 5 Pan Motor Speed
Film M Step 5 Cycle Type Selection
Film M Step 5 Dosing Off Time
Film M Step 5 Dosing On Time
Film M Step 5 Time
Film M Step 5 Dosing Cycle
Post J Selection Yes No
Film M Step 1 Dosing Pump Speed
Film M Step 2 Dosing Pump Speed
Film M Step 3 Dosing Pump Speed
Film M Step 4 Dosing Pump Speed
Film M Step 5 Dosing Pump Speed
Post J Inlet Air Temperature
Post J Exhaust Air Temperature
Post J Inlet Blower Speed
Post J Exhaust Blower Speed
Post J Pan Motor Speed
Post J Pan Off Time
Post J Pan On Time
Post J Cycles

5.5.6 After filling parameters as per BMR, press 'SAVES'. Screen shown message

?	X
Data record 'Recipe Name' of recipe FILM RECIPE already Exist. Overwrite data record.	
<input type="button" value="YES"/>	<input type="button" value="NO"/>

5.5.7 On lower side of screen message shown 'DATA RECORD SAVE'.



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5.5.8 Batch enters parameters to be shown on 'PARAMETERS' mode. Screen shows

G M/C OVERVIEW		GAC1700		
LOGIN NAME	<input type="text"/>	LOGIN LEVEL	<input type="text"/>	
BATCH DETAILS			MODE	
PRODUCT NAME	<input type="text"/>	PRODUCT CODE	<input type="text"/>	MAINTENANCE
BATCH NUMBER	<input type="text"/>	LOT NUMBER	<input type="text"/>	MANUAL
OPERATOR NAME	<input type="text"/>			AUTO
TEMPERATURE PARAMETERS			PARAMETERS	
INLET AIR TEMPERATURE MAXIMUM +ve TOL.	<input type="text"/>			RECIPE MGMT.
INLET AIR TEMPERATURE MAXIMUM -ve TOL.	<input type="text"/>			MAKE/ SELECT
EXHAUST AIR TEMPERATURE MAXIMUM +ve TOL.	<input type="text"/>			SYSTEM
EXHAUST AIR TEMPERATURE MAXIMUM -ve TOL.	<input type="text"/>			TRENDS
GENERAL PARAMETERS			M/C OVERVIEW	
HEPA FILTER DP HIGH HIGH	<input type="text"/>			ALARM HISTORY
HEPA FILTER DP HIGH	<input type="text"/>			SECURITY MGMT.
HEPA FILTER DP LOW	<input type="text"/>			RESET
PAN DP PID	<input type="text"/>		▼	LOGOUT
PAN DP SET VALUE	<input type="text"/>			H/W DIAGNOSIS
PAN DP +ve AND -ve TOL.	<input type="text"/>			INPUTS-OUTPUTS
SOLUTION AGITATOR OFF TIME	<input type="text"/>			DATE & TIME
SOLUTION AGITATOR ON TIME	<input type="text"/>			
PRINT INTERVAL	<input type="text"/>			
PAN JAM FAULT BYPASS	<input type="text"/>		▼	
PROCESS CONTROL BY	<input type="text"/>		▼	
				<PREV
				NEXT>
				ALARM ACK

5.5.9 By pressing 'NEXT' on parameters 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'.

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



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5.5.11 Message shown as

?	X
Do you really want to delete data record please check in recipe FILM RECIPE?	
<input type="button" value="YES"/>	<input type="button" value="NO"/>

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, Solution Agitator, Pause Dosing, Print and PID setting to be done as required.

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

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

5.6.5 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.

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

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

5.7 AUTO MODE SETTING:

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

5.7.2 Select the recipe from the Make/ Select, screen for the desired product.

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.



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- 5.7.5 By pressing 'START' sequentially turning ON the scrubber followed by exhaust blower after the purified 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 shut 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 in Reverse direction. On every rotation scooping is affected.
- 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):

- 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



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- 6.6 MMI : Man Machine Interface
6.7 Mpa : Mili pascal
6.8 WIP : Wash In Place
6.9 RPM : Round Per Minute

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-1700).		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
9.2 **Controlled copy (s)** : Production department (02), Quality Assurance (01)
9.3 **Reference copy (s)** : Production department (02)

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	



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ANNEXURE I CLEANING CHECKLIST OF GANSCOATER (GAC-1700)

Equipment Name	Ganscoater (GAC-1700)	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.	Follow the instruction given in MMI Parameter and start the cleaning.		
6.	In case of coating solution contains enteric coating polymer/methacrylic acid: Repeat the step sr. no.4 and 5 with sink filled by 0.4 % NAOH solution instead of water and finally repeat the step sr. no. 4 and 5 with water.		
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.	By pressing start Water cycle, Air purge cycle and Drying & Cooling cycle takes place.		
12.	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.		
13.	As WIP time gets over drain valve SV-8 will open for a set time and get closed when drain time complete.		
14.	Air Purge Cycle: - during this cycle inlet valve have to keep close.		
15.	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.		
16.	Drying & Cooling Cycle: - system checks for the exhaust temperature. Once the exhaust temperature is reached the drying cycle start.		
17.	After completion of all the cycles in WIP alarm triggered as 'WIP Cycle Over'.		
18.	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.		
19.	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.		
20.	For cleaning of silicon tubes and Spray gun		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Ganscoater (GAC-1700)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

21.	Remove the product inlet & outlet tubes from the nozzles of the Solution feed vessel.	
22.	Dip these tubes into purified water.	
23.	Remove the nozzles from the spray guns.	
24.	Reduce the atomizing air pressure to zero on HMI & hold a poly-bag in front of spray guns.	
25.	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.	
26.	Scrub the pan with nylon brush to soften the adhered matters and re-clean with fresh purified water if necessary.	
27.	Drain the water from the sink by opening valve at rear of Main pain Unit. And confirm complete draining of water.	
28.	Remove the water droplets from the equipment with help of compressed air if necessary.	
29.	Finally Rinse the cleaned parts with 50-70 liters of purified water.	
30.	In case of coating solution contains enteric coating polymer/methacrylic acid then repeat the step sr.no.29 with 50-70 litres 0.4 % NAOH solution and followed by with 50-70 litres purified water.	
31.	Wipe the inner surface of pan, outer surface of the body of coater with lint free duster	
32.	The Baffles, Gun, Dosing rake, Plenums, Solution holding tank and peripherals to be take	
33.	Dedust the control panel, peristaltic pump, and WIP pump with clean lint free cloth	
34.	Re-assemble the baffles, plenums, side panels and guns.	
35.	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.