



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for cleaning and operation of auto coater (Sejong).

### 2.0 SCOPE:

2.1 This SOP is applicable to the cleaning and operation of auto coater and its accessories in the production area.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation Auto coater

3.2 Production Officer / Executive : Checking cleaning and operation

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 Remove "EQUIPMENT STATUS" label and affix dully filled "UNDER CLEANING" label to the machine as per SOP "STATUS LABELING"

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 De dust the external surface of auto coater, solution tank with clean lint free cloth.

5.1.4 De dust 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.

5.1.5 Collect the remaining quantity of coating solution from the solution tank in a double poly bag and send it to ETP with disposed tablets



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 5.1.6 Rinse the solution tank with excess quantity of purified water to remove the previous adhere material.
- 5.1.7 Clean the spray guns and solution supply pipe by flushing the excess quantity of purified water through them. And dismantle the solution supply pipes and dry them with compressed air.
- 5.1.8 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.
- 5.1.9 Clean the area as per SOP "CLEANING OF PRODUCTION AREA".
- 5.1.10 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 Change over of product with different actives / colour / ascending potency / descending potency or after maintenance of contact parts.**

- 5.2.1 Remove "EQUIPMENT STATUS" label and affix dully filled "UNDER CLEANING" label to the machine as per SOP "STATUS LABELING" and record the cleaning observations 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 Turn 'ON' the control panel and open the 'WIP' screen.
- 5.2.4 Open the door of auto coater and touch 'GUN SLIDING OUT' on MMI. Gun assembly will slide out.
- 5.2.5 Disconnect the atomization, cylinder air and solution supply pipes from individual gun.
- 5.2.6 Remove the guns from the gun assembly.
- 5.2.7 Install cleaning nozzle assembly on the gun assembly and make connection with WIP supply pipe.
- 5.2.8 Open the side panels and unbolt all baffles from the Pan inside.
- 5.2.9 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.
- 5.2.10 Follow the instruction given in MMI Parameter and start the cleaning.
- 5.2.11 **Method of cleaning in case of coating solution contains enteric coating polymer/ methacrylic acid:**



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 5.2.12 Open WIP screen on MMI. Turn 'ON' the purified water supply. Touch 'WIP START' on MMI. Start the pan then start the spray WIP pump will start and water will start.
- 5.2.13 Open film coating screen and turn 'ON' the pan.
- 5.2.14 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).
- 5.2.15 Repeat the step 5.2.9 and 5.2.10 with sink filled by 0.4 % NAOH solution instead of purified water and finally repeat the step 5.2.9 and 5.2.10 with purified water.
- 5.2.16 Ensure that whole pan has wet properly and then Stop the pan.
- 5.2.17 Scrub the pan with nylon brush to soften the adhered matters.
- 5.2.18 Ensure the sharp edges of baffles, inlet and exhaust ducts have been cleaned properly.
- 5.2.19 Continue the water spraying till all the adhered and soften matters washed away.
- 5.2.20 Finally rinse the auto coater with the 40-60 liters of purified water.
- 5.2.21 In case if coating solution (enteric coating polymer/methacrylic acid) remains then clean with 50-70 liters 0.4 % NAOH solution and followed by with 50-70 liters purified water.
- 5.2.22 Start the auto coater for 30-40 minutes at 70 °C to dry the pan.
- 5.2.23 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).
- 5.2.24 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 brush to remove the any color residue. Finally dry the guns and their parts with compressed air.
- 5.2.25 Disconnect the compressed air supply from solution tank. Rinse the tank with purified water.
- 5.2.26 Open the drain pipe and clean it with nylon bottle brush and flush with purified water till whole contains of previous product are washed away.
- 5.2.27 Flush the solution tank with purified water till whole contains of previous product are Washed away. Finally wipe the inner and outer surface with lint free duster dipped in 70 % v/v IPA followed by dry lint free cloth.
- 5.2.28 Clean the sides and top of auto coater with clean wet lint free cloth.
- 5.2.29 Ensure that pan is dried properly.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

5.2.30 Place the cartage filter in polybag and clean it with compressed air blow in reverse direction. Collect the powder present in rejection tray in same polybag and then affix 'SCRAP' label duly signed and dated and sent the rejection to ETP for further processing. Clean the rejection tray with nylon scrubber and purified water. Finally wipe with 70 % IPA solution.

5.2.31 Stop the auto coater.

5.2.32 Wipe the inner and outer surface of solution tank, pan, sides and top of with 70 % w/w IPA (70 ml IPA + 30 ml water).

5.2.33 Dedust the control panel, peristaltic pump and WIP pump with clean lint free cloth.

5.2.34 Clean the area as per SOP "CLEANING OF PRODUCTION AREA".

5.2.35 Affix 'CLEANED' label duly filled and signed on the equipment.

5.2.36 If the machine remains idle for more than 72 hours after cleaning, then replace a 'CLEANED' status label with 'UNDER CLEANING' status label and clean the machine with dry lint free duster followed by wiping with 70% w/w IPA solution before using the machine and affix 'CLEANED' label duly filled and signed on the equipment  
Record the cleaning end time 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, same potency and of similar product with ascending potency. 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 / colour / 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".



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 5.4 MACHINE SETTING:

- 5.4.1 Ensure that the equipment and area is cleaned as per SOP. Affix 'EQUIPMENT STATUS' 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".
- 5.4.2 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 NLT 0.4 Mpa.
- 5.4.4 Set the all spray guns on the retractable arm.
- 5.4.5 Connect the silicon tubes with the peristaltic pump, retractable arm with the spray guns end and with the holding tank at the other end.

### 5.5 OPERATION:

- 5.5.1 Turn the power 'ON/OFF' key to 'OFF' position. MMI will turn OFF.
- 5.5.2 Turn Control 'ON/OFF' switch on control panel to 'ON' position. Main screen will open on MMI.
- 5.5.3 Touch the "Login" icon.
- 5.5.4 Three level password screens will appear

Level	
User ID	<input type="text"/>
Password	<input type="password"/>
<input type="button" value="OK"/>	<input type="button" value="Cancel"/>

- 5.5.5 There are three levels of Password:
  - Level 1.** Operator can operate machine in auto mode after the recipe has been loaded from recipe mode and can use the existing recipe loaded in HMI.
  - Level 2.** Supervisor can operate machine in auto/manual mode and can load existing recipe from recipe mode.
  - Level 3.** Manager can operate the machine in maintenance mode, can create/edit/Delete recipe from HMI.
- 5.5.6 Enter the respective allocated password.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

5.5.7 “AUTO COATING SYSTEM” screen will open having following menu.

- Product setting
- Mode selection
- Recipe
- Sugar coating
- WIP
- Film Coating
- Temperature offset
- Change password
- Welcome

**Note :**

During coating operation check the in process of spray rate, the frequency shall be as per BMR. After completion of coating activity, average spray rate shall be calculated. The calculation of average spray rate is as mentioned below-

$$C \times 1000$$

Average spray rate=-----

$$\text{Time period (in minutes)} \times \text{NS}$$

Where, C = Coating solution consumed (in Kg).

NS = No. of spray guns.

### 5.6 RECIPE LOAD/EDIT

5.6.1 Touch the “RECIPE” Icon. New screen will appear.

5.6.2 For new recipe preparation touch the “NEW” icon on screen.

5.6.3 Copy of present master recipe will appear.

5.6.4 Touch the “EDIT” icon to edit the recipe name as per BMR.

5.6.5 Enter the following process parameter shows in below part of screen as per BMR

- Inlet blower RPM
- Exhaust blower RPM
- Pan RPM
- Inlet Temp.
- Bed Temp.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- Exhaust Temp.
- Pan off time (Sec.)
- Pan on time (Sec.)
- Dosing RPM
- Dosing off time (Sec.)
- Dosing on time (Sec.)
- Operator Name
- Mode
- Product Code
- Product name
- Batch No.
- Lot no.
- Print interval
- Inlet Temp. High offset
- Inlet Temp. Low offset
- Exhaust Temp. High offset
- Exhaust Temp. Low offset

5.6.6 Touch the “SAVE” icon to save the recipe.

5.6.7 Touch the “LOAD” icon to load the recipe.

5.6.8 Press “MAIN” icon, main screen will appears.

### 5.7 AUTO MODE OPERATION

5.7.1 Enter the respective allocated password. “AUTO COATING SYSTEM” screen will appear. Touch the recipe icon.

5.7.2 Load the respective recipe as per BMR.

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

5.7.4 Touch the “FILM COATING” icon.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

5.7.5 Operation screen will appear with following menu.

- Supply velocity
- Bed temp.
- Inlet Temp. Set
- Inlet Temp. Act.
- Exhaust Temp. Set
- Exhaust Temp. Act.
- Main coater
- Exhaust blower
- Inlet blower
- Intermittent drive
- Agitator
- Gun Sliding system
- Main
- Spray Screen
- Alarm Screen
- Dosing pump with FWD,REV and STOP
- Dosing pump set RPM
- Auto
- Man

5.7.6 For auto mode operation touch AUTO on the screen in MMI.

5.7.7 Touch "START" icon mentioned in above mentioned parameter to start the operation.

5.7.8 The Operation screen which appears will show the actual parameters at that time of the coating running cycle.

5.7.9 Touch "STOP" icon mentioned in above mentioned parameter to stop the operation.

5.7.10 Touch "Main" icon to exit from the auto mode.

### 5.8 MANUAL MODE OPERATION:

5.8.1 Enter the respective allocated password. "AUTO COATING SYSTEM" screen will appear.

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

5.8.3 Touch the "FILM COATING" icon. Operation screen will appear.





# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 5.8.4 For manual operation touch "MAN" on the screen in MMI.
- 5.8.5 Enter the value as per BMR in icon shows in operation screen.
- 5.8.6 Check the spray rate , Switch" ON' the gun and collect the solution in a beaker for one minute and weight the beaker on balance, calculate and record in BMR.repeat the procedure for next gun if applicable.
- 5.8.7 Load the core tablets in the pan with carefully. Touch 'GUN SLIDING IN' on MMI. Gun assembly will slide inside. Ensure the distance between tablet bed and spray gun should be as per BMR.
- 5.8.8 Fix the bed temperature sensor such that it should not touch the baffles of pan and coating solution should not get sprayed over it during coating operation.
- 5.8.9 Close the door of auto coater.
- 5.8.10 Ensure the discharge valve of solution tank is closed. Load the coating solution in the solution tank and lock the lid properly.
- 5.8.11 Touch 'AGITATOR START' on MMI. Agitator shall start.
- 5.8.12 Touch 'MAIN COATER START' and turn the pan 'ON/OFF' knob to 'ON' position. Pan will start running as per set RPM.
- 5.8.13 Wait till tablet bed does not reach the temperature specified in BMR.
- 5.8.14 Set atomization pressure for gun-1, gun-2 and Gun-3. by operating the pressure gauge knob Ensure that the air flow is approximately same for all three guns.
- 5.8.15 Touch 'SPRAY SCREEN' on MMI. Film spray screen will open.
- 5.8.16 Turn 'ON' gun-1, 2 and 3 by touching respective gun on MMI.
- 5.8.17 Press spray 'ON' on control panel. Spray will start.
- 5.8.18 Touch "START" icon in above mentioned parameter to start the operation.
- 5.8.19 The Operation screen which appears will show the actual parameters at that time of the coating running cycle.
- 5.8.20 Touch "STOP" icon mentioned in above mentioned parameter to stop the operation.
- 5.8.21 To take samples of coated tablets for in-process checking stop the peristaltic pump. Open the door and collect the sample.
- 5.8.22 Close the door. Restart the peristaltic pump by pressing 'START' key on peristaltic pump.
- 5.8.23 On completion of coating operation press 'STOP' on peristaltic pump. Coating solution spraying will stop. Turn 'OFF' the agitator.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 5.8.24 Let the supply and exhaust blower start till tablet bed dry completely.
- 5.8.25 Touch "Main" icon to exit from the manual mode.
- 5.8.26 Touch 'ALARM SCREEN' on MMI. Alarm screen will open. Touch 'RESET' on control panel. MMI will restart and opening screen will open. Touch 'FILM COATING' on MMI. Operation screen will open.
- 5.8.27 Turn pan 'ON/OFF' knob to 'OFF' position. To stop exhaust and supply touch 'STOP' for respective parameter. Exhaust blower and supply blower will stop.
- 5.8.28 Open the door and adjust the bed temperature sensor such that it does not touch the discharge chute. Assemble the discharge chute in place and close the door. Place clean pre-labeled, double polybag lined SS bin below the discharge. Turn ON the pan discharge will start.
- 5.8.29 Ensure the pan is discharged completely. Switch on the lamp if required.
- 5.8.30 Turn pan 'ON/OFF' knob to 'OFF' position. Turn the power 'ON/OFF' key to 'OFF' position. MMI will turn OFF.
- 5.8.31 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".

**Note:** Loading of core tablets in coating pan to be done carefully by Teflon scoop.

### 6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 w/w : Weight / Weight
- 6.4 ml : Milliliter
- 6.5 BMR : Batch Manufacturing Record
- 6.6 MMI : Man Machine Interface
- 6.7 SOP : Standard Operating Procedure
- 6.8 Mpa : Millipascal
- 6.9 WIP : Wash In Place



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

6.10 ETP : Effluent Treatment Plant

6.11 NLT : Not Less Than

### 7.0 REFERENCES (S):

7.1 SOP, Making entries in equipment usage and cleaning log sheet.

7.2 SOP, Cleaning of Production Area.

7.3 SOP, Status Labeling

### 8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Cleaning checklist of Auto coater		Logbook
Annexure - II	Recipe parameters for Sejong		Controlled Copy

### 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 (01)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change control no.	Reason (S) For Revision	Detail of Revision	Effective Date
01	00	NA	New SOP	NA	NA

## ANNEXURE I

### CLEANING CHECKLIST OF AUTO COATER (Sejong)



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

<b>Name of the Equipment</b>	<b>AUTO COATER (Sejong)</b>		
<b>Equipment I.D. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

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.	Clean the sharp edges of baffles, inlet and exhaust ducts.	
4.	Continue the water spraying till all the adhered and soften matters washed away.	
5.	Open the side panels and unbolt all baffles from the Pan inside.	
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.	
7.	Follow the instruction given in MMI Parameter and start the cleaning.	
8.	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)	
9.	Repeat the step filled by 0.4 % NAOH solution instead of purified water and finally repeat the step with purified water.	
10.	Finally rinse the auto coater with the 40-60 liters of purified water.	
11.	Start the auto coater for 30-40 minutes at 70 °C to dry the pan.	
12.	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.	
13.	Disassemble the guns and clean the each part of gun with purified water. After then Clean	



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto Coater	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

S.No.	Activity	Activity Performed
	the guns and its parts with 70 % v/v IPA solution and nylon brush to remove the any color residue. Finally dry the guns and their parts with compressed air.	
14.	Disconnect the compressed air supply from solution tank. Rinse the tank with purified water.	
15.	Open the drain pipe and clean it with nylon bottle brush and flush with purified water till whole contains of previous product are washed away.	
16.	Flush the solution tank with purified water till whole contains of previous product are washed away. Finally wipe the inner and outer surface with lint free duster dipped in 70 % v/v IPA followed by dry lint free cloth.	
17.	Clean the sides and top of auto coater with clean wet lint free cloth.	
18.	Ensure that pan is dried properly.	
19.	Place the cartage filter in polybag and clean it with compressed air blow in reverse direction. Collect the powder present in rejection tray in same polybag and then affix 'SCRAP' label duly signed and dated and sent the rejection to ETP for further processing Clean the rejection tray with nylon scrubber and purified water. Finally wipe with 70 % IPA solution.	
20.	Stop the auto coater.	
21.	Wipe the inner and outer surface of solution tank, pan, sides and top of with 70 % w/w IPA (70 ml IPA + 30 ml water).	
22.	Dedust the control panel peristaltic pump and WIP 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.

### ANNEXURE II RECIPE PARAMETER FOR SEJONG



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Production

**SOP No.:**

**Title:** Cleaning & Operation of Auto Coater

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

<b>Program Code:</b>	<b>Recipe Parameter Verified By: Sign. &amp; Date (Production)</b>		
<b>Parameter</b>	<b>Specification</b>	<b>Set value</b>	<b>Observation</b>
<b>Spray rate</b>			
Inlet Blower RPM			
Exhaust Blower RPM			
Pan RPM			
Inlet Temp.			
Bed Temp.			
Exhaust Temp.			
Pan Off Time			
Pan on Time			
Dosing RPM			
Dosing off time			
Dosing on time			

\$ Set value to be verified by the Production officer.

\*Observation to be recorded by the operator.

**Remarks:**