



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of 35- Station Double Rotary Compression Machine	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of 35-Station Double Rotary Compression Machine.

### 2.0 SCOPE:

This SOP applicable to the Cleaning of 35-Station Double Rotary Compression Machine in the 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

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

- 5.1.1 Affix dully filled "TO BE CLEANED" status label equipment with date and signature of the Production Officer as per SOP.
- 5.1.2 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.3 Ensure that the main power supply is put OFF and press the emergency switch.
- 5.1.4 Release the hydraulic pressure and remove the tablets from the bottom parts of the machine and clean it with the help of lint free cloth.
- 5.1.5 Remove all the powder from hopper & from the machine carefully.



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5.1.6 Dismantle carefully the following parts.

Feed hopper

Turret guards

Tablet collecting chutes

Upper punch & Lower punch

5.1.7 Remove the powder from the machine with the help vacuum cleaner.

5.1.8 Clean the machine feed hopper, turret guard, tablet-collecting chute with relevant bolts and upper/lower punches thoroughly with dry lint free cloth.

5.1.9 After completion of cleaning process, get it checked by production officer/QA officer.

5.1.10 Set the disassembled cleaned parts.

5.1.11 Replace the "TO BE CLEANED" status label with "CLEAED" status label with date and signature of the Production/QA Officer.

5.1.12 Enter the cleaning completion time in equipment usage log sheet as per SOP.

### 5.2 TYPE B

**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 Follow the step 5.1.1 to 5.1.3.

5.2.2 Unscrew the panel covering on the front side and the side covers.

5.2.3 Dry clean the machine control panel from outside and inside vacuum cleaner and with dry lint free cloth.

5.2.4 Clean beneath the compression machine and fit the panel covering back in place.

5.2.5 Dismantle the feed hopper, feeders, circulating arms, feed frame, upper punch guards, and suction nozzles

5.2.6 Dismantle the scrapper blade, ejection plate, re-circulating bend & Put all the dismantled parts in a virgin poly affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.

5.2.7 Clean all the above parts first with 10-15 liters of purified water, then clean by using nylon scrubber and wash with 30 – 40 liters of purified water.

5.2.8 Dismantle the feeder assembly and wash with purified water.

5.2.9 Finally rinse all the above washed parts with 20-25 liters of purified water.

5.2.10 Wipe all the cleaned parts with lint free cloth dipped in IPA.

5.2.11 Dry all the parts using a dry lint free cloth.



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- 5.2.12 Keep all the dried parts on a cleaned stainless steel pallet and cover it with a virgin polythene bag with a status label as "CLEANED" with date and signature of the production officer and transfer them to respective compression area.
- 5.2.13 Open the acrylic guard and clean with a dry lint free cloth.
- 5.2.14 Remove the upper punches one by one and clean with a lint free cloth and keep in a tray.
- 5.2.15 Remove anti- turning plugs and tension plate.
- 5.2.16 Remove the plug by turning clockwise direction.
- 5.2.17 Remove the lower punches through the hole one by one, wipe to clean and keep in a SS tray.
- 5.2.18 Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.
- 5.2.19 Clean the upper punch pocket using a dry nylon brush first and then clean with a nylon brush dipped in IPA and dry the punch pocket using a cleaned lint free cloth.
- 5.2.20 Unscrew the die locks and insert the small S.S. bar in lower punch bore and hammer at the bottom of die to remove it out.
- 5.2.21 Remove all the dies and keep in a SS tray.
- 5.2.22 Clean with nylon brush dipped in IPA and dry with a cleaned lint free cloth.
- 5.2.23 Remove the upper and lower cam tracks and clean it with a lint free cloth dipped in IPA.
- 5.2.24 Clean the lower punch barrels using nylon brush dipped in IPA and then clean with a cleaned lint free cloth.
- 5.2.25 Clean all the die cavities, die plate and inside portion of turret with a cleaned lint free cloth and then clean with a lint free cloth dipped in IPA.
- 5.2.26 Dry the die cavity and turret with a dry lint free cloth.
- 5.2.27 Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.
- 5.2.28 Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.
- 5.2.29 Dry the pipe with the help of compressed air.
- 5.2.30 Fit the side covers of the compression machine back in place.
- 5.2.31 Inform the engineering department to clean the return air riser filter.
- 5.2.32 Replace the "TO BE CLEANED" status label with dully filled "CLEANED" status label with date and Signature of the production officer/QA officer.
- 5.2.33 Enter the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.34 Clean the area as per SOP.



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5.2.35 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP.

5.2.36 Enter the cleaning completion time in equipment usage log sheet as per SOP.

5.2.37 Record the cleaning activity in cleaning checklist.

### 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, de-dusting 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.

### 5.4 Machine setting:

5.4.1 Ensure that the equipment and area is cleaned and place 'UNDER PROCESS' label duly filled and signed on the machine and record all the observations in equipment usage log as per SOP.

5.4.2 Collect the punch set as per specifications in respective BMR from compression spare room and record the issuance in the Die Punches Utilization Record. SOP.

5.4.3 Clean the die punch set with 70 % v/v IPA (70 ml IPA + 30 ml water) before installing on the compression machine.

### 5.5 Setting of round die punches:

5.5.1 Fix the dies in die cavities by using a Tommy.

5.5.2 Ensure that the die is fixed at the same level with the turret.

5.5.3 Place lower punch in lower punch bores such that it rest on the cam and tighten the anti turning Teflon plugs.

5.5.4 Place upper punch in upper punch bores.

5.5.5 Turn the flywheel and set all die punches on compression machine by following step no. 5.4.1 to 5.4.5.



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5.5.6 Ensure that the punch should move freely inside the punch bore and die during the fixing of upper and lower punches.

### **5.6 Setting of other than round die punches:**

5.6.1 Fix the die in die cavity.

5.6.2 Place the upper punch in upper punch bore and hold it with hand. Align the tip of the punch in the respective die and tap gently with the upper punch to position the die in the cavity.

5.6.3 Ensure that the upper punch is freely moving in the respective die.

5.6.4 Remove the upper punch and fix the dies in die cavities by using a Tommy.

5.6.5 Ensure that the die is fixed at the same level with the turret.

5.6.6 Tighten the die locking screws. Cover the die locks with the SS cover provided.

5.6.7 Ensure that the upper punch is free in the respective die.

5.6.8 Remove the take off piece from the cam track.

5.6.9 Rest the upper punch on cam track. Turn the flywheel and set all the dies and punches in same fashion.

5.6.10 Remove the upper punch near the take off piece slot and fix the take off piece.

5.6.11 Place the upper punch back to the upper punch bore and tighten the punch locking screw.

5.6.12 Place lower punches in lower punch bores.

5.6.13 Fix the anti turning Teflon plugs by tightening the spring plates.

### **5.7 Setting of feed frame and hopper:**

5.7.1 Initially keep cam loose and after setting two or three die punches, fix the cam.

5.7.2 Ensure cam is not touching any part of machine and then fix the dozer.

### **5.8 Manual Operation:**

5.8.1 Align vertical de-duster next to the outlet chute of the compression machine and metal detector next to the outlet chute of the vertical de-duster.

5.8.2 Place SS container lined with double polybag next to the metal detector outlet chute.

5.8.3 Load granules in the RHS and LHS hopper and cover both hoppers.

5.8.4 Turn 'ON' the main switch.

5.8.5 Insert key in reset lock and turn to reset position. Screen will show zero product count.

5.8.6 Turn flywheel to check any loose part.

5.8.7 Press 'START' button on control panel. Turn engage/disengage lever to engage position. Machine will start.

5.8.8 To run the machine in inch mode engage and disengage the clutch alternately.



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- 5.8.9 Check the weight then thickness and then hardness of individual tablet.
- 5.8.10 Ensure that weight, thickness and hardness of individual tablet is within limit specified in respective BMR. If not,
- 5.8.10.1 Set the by turning weight adjustment lever in clockwise direction to increase the weight and anticlockwise direction to decrease the weight.
- 5.8.10.2 Set the thickness by turning tablet thickness lever in clockwise direction to increase the thickness and to decrease the thickness turn the lever in anticlockwise direction.
- 5.8.11 After setting weight and thickness check friability and DT of the tablets as per specification in respective BMR for LHS and RHS station.
- 5.8.12 Record all the observations in respective BMR.
- 5.8.13 Reject the tablets compressed during machine setting.
- 5.8.14 Operate the metal detector and vertical de-duster as per SOP.
- 5.8.15 To increase turret RPM turn rotary RPM knob in clockwise direction and to decrease the turret RPM turn rotary RPM knob in anticlockwise direction.
- 5.8.16 Press 'STOP' to stop the machine.
- 5.8.17 At the end of operation affix 'TO BE CLEANED' label duly filled and signed on the machine and record all the observation in equipment usage log sheet as per SOP.
- 5.8.18 Record all the observations in respective BMR.
- 5.8.19 Reject the tablets compressed during machine setting.
- 5.8.20 Operate the metal detector and vertical de-duster as per SOP.
- 5.8.21 Ensure the setting of scrapper is so that tablet should not break during initial machine setting.  
First two round tablets shall be destroy at every start up of compression machine.



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### 6.0 ABBREVIATION (S):

BMR	:	Batch manufacturing record
QA	:	Quality Assurance
SS	:	Stainless Steel
SOP	:	Standard operating procedure
IPA	:	Iso propyl alcohol
ml	:	Milliliter
v/v	:	Volume/Volume
MMI	:	Man machine interface
DT	:	Disintegration test
SS	:	Stainless steel
kN	:	Kilo Newton
BMR	:	Batch Manufacturing Record

### 7.0 REFERENCES (S):

- SOP: Making entries in equipment usage and cleaning log sheet.
- SOP: Cleaning And Operation of metal detector and vertical de-duster
- SOP: Issuance, use and retrieval of punches and dies.
- SOP: Cleaning of production area
- SOP: Status Labeling

### 8.0 ANNEXURE (S):

**Annexure I:** Cleaning checklist

### 9.0 DISTRIBUTION:

**Master Copy** : Quality Assurance

**Controlled copy (S):** Production department, Quality Assurance

**Reference copy (S):** Production department



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### ANNEXURE I

#### CLEANING CHECKLIST OF COMPRESSION MACHINE (35 STATION)

<b>Name of the Equipment</b>	COMPRESSION MACHINE (35 STATION)		
<b>Equipment ID. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

S.No.	Activity	Activity performed
1.	Unscrew the panel covering on the front side and the side covers.	
2.	Dry clean the machine control panel from outside and inside using dust collector hose and with dry lint free cloth.	
3.	Clean beneath the compression machine and fit the panel covering back in place.	
4.	Dismantle the fed, hopper view glasses, feeders, circulating arms, acrylic guard, feed frame, dismantle the stand provided for resting the feeders, upper punch guards, suction nozzles and transfer its to washing area.	
5.	Dismantle the scrapper blade, ejection plate, re-circulating blade, feeder gaskets & feeder cover	
6.	Clean all the above parts first with 10-15 liters of purified water, then clean by using nylon scrubber and wash with 30 – 40 liters of purified water.	
7.	<b>Dismantle the feeder assembly including the acrylic plate and wash with purified water.</b>	
8.	Finally rinse all the above washed parts with 20-25 liters of purified water.	
9.	Wipe all the cleaned parts with lint free cloth dipped in 70% v/v IPA.	
10.	Dry all the parts using a dry lint free cloth.	
11.	Keep all the dried parts in a cleaned stainless steel pallet and cover it with a cleaned polythene bag with a status label as “CLEANED” with date and signature of the production officer keep in respective compression area.	
12.	Open the acrylic guard and clean with a dry lint free cloth.	
13.	Remove the upper punches one by one and clean with a lint free cloth and keep its in a tray.	
14.	Remove the anti- turning plugs and tension plate.	
15.	Remove the plug by turning clockwise direction.	
16.	Remove the lower punches through the hole one by one, wipe to clean and keep in a SS tray.	





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S.No.	Activity	Activity performed
17.	Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.	
18.	Clean the upper punch pocket using a dry nylon brush first and then clean with a nylon brush dipped in 70% v/v IPA and dry the punch pocket using a cleaned lint free cloth.	
19.	Unscrew the die locks and insert the small S.S. bar in lower punch bore and hammer at the bottom of die to remove it out.	
20.	Remove all the dies and keep in a SS tray.	
21.	Clean with nylon brush dipped in 70% v/v IPA and dry with a cleaned lint free cloth.	
22.	Remove the upper and lower cam tracks and clean it with a lint free cloth dipped in 70% v/v IPA.	
23.	Clean the lower punch barrels using nylon brush dipped in IPA and then clean with a cleaned lint free cloth.	
24.	Clean all the die cavities, die plate and inside portion of turret with a cleaned lint free cloth and then clean with a lint free cloth dipped in 70% v/v IPA.	
25.	Dry the die cavity and turret with a dry lint free cloth.	
26.	Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.	
27.	Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.	
28.	Dry the pipe with the help of compressed air.	
29.	Fit the side covers of the compression machine back in place.	

**Checked By (Prod.)**  
**Sign/Date**

**Verified By (QA)**  
**Sign/Date**

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