



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of 55-Station Double Rotary Compression Machine	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of 55-station double rotary Compression machine.

### 2.0 SCOPE:

This SOP applicable to the cleaning of 55-station double rotary compression machine in the production area.

### 3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Production Officer / Executive: Checking cleaning and operation

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 change over from one batch to next batch of the same product, same potency.**

- 5.1.1 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.
- 5.1.2 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.3 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.
- 5.1.4 Remove all the powder from hopper & from the machine carefully.
- 5.1.5 Dismantle carefully the following parts.  
Feed hopper, Turret guards, Tablet collecting chutes, Upper punch & Lower punch
- 5.1.6 Remove the powder from the machine with the help of vacuum cleaner.
- 5.1.7 Clean the machine feed hopper, turret guard, tablet-collecting chute with relevant bolts and upper/lower punches thoroughly with dry lint free cloth.
- 5.1.8 After completion of cleaning process, get it checked by production office/QA officer.
- 5.1.9 Set the disassembled cleaned parts.
- 5.1.10 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine.
- 5.1.11 Enter the cleaning completion time in equipment usage log as per SOP.



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### 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 "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.
- 5.2.2 Ensure that the main power supply is put OFF and press the emergency switch.
- 5.2.3 Unscrew the panel covering on the front side and the side covers.
- 5.2.4 Dry clean the machine control panel from outside and inside using vacuum cleaner and with dry lint free cloth.
- 5.2.5 Clean beneath the compression machine and fit the panel covering back in place.
- 5.2.6 Dismantle the feed hopper view glasses, feeders, circulating arms, feed frame, upper punch guards, suction nozzles and transfer its to washing area.
- 5.2.7 Dismantle the scrapper blade, ejection plate, re-circulating bend, feeder gaskets & feeder cover & Put all the dismantled parts in a virgin poly affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.
- 5.2.8 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.
- 5.2.9 Dismantle the feeder assembly including the acrylic plate and wash with purified water.
- 5.2.10 Finally rinse all the above washed parts with 20-25 liters of purified water.
- 5.2.11 Wipe all the cleaned parts with lint free cloth dipped in 70 % v/v IPA.
- 5.2.12 Dry all the parts using a dry lint free cloth.
- 5.2.13 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.
- 5.2.14 Open the acrylic guard and clean with a dry lint free cloth.
- 5.2.15 Remove the upper punches one by one and clean with a lint free cloth and keep in a tray.
- 5.2.16 Remove anti- turning plugs and tension plate.
- 5.2.17 Remove the plug by turning clockwise direction.
- 5.2.18 Remove the lower punches through the hole one by one, wipe to clean and keep in a SS tray.
- 5.2.19 Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.
- 5.2.20 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.
- 5.2.21 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.



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- 5.2.22 Remove all the dies and keep in a SS tray.
- 5.2.23 Clean with nylon brush dipped in 70% v/v IPA and dry with a cleaned lint free cloth.
- 5.2.24 Clean the upper and lower cam tracks with a lint free cloth dipped in 70% v/v IPA.
- 5.2.25 Clean the lower punch barrels using nylon brush dipped in 70% v/v IPA and then clean with a cleaned lint free cloth.
- 5.2.26 Clean all the die cavities die plate and inside portion of turret with cleaned lint free cloth and then clean with a lint free cloth dipped in 70% v/v IPA.
- 5.2.27 Dry the die cavity and turret with a dry lint free cloth.
- 5.2.28 Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.
- 5.2.29 Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.
- 5.2.30 Dry the pipe with the help of compressed air.
- 5.2.31 Fit the side covers of the compression machine back in place.
- 5.2.32 Inform the engineering department to clean the return air riser filter.
- 5.2.33 Replace the “UNDER “CLEANING” status label with “CLEANED” status label with date and Signature of the production officer/QA officer.
- 5.2.34 Record the cleaning activity in equipment usage log as per SOP.
- 5.2.35 Record the cleaning checklist as per Annexure –I.

### 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.
- 5.3.2 Cleaning (Dedusting of machine with vacuum cleaner and dry lint free cloth) is applicable in case of at the end of working day

**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.



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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.

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. 5.5.1 to 5.5.4.

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 takeoff 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 takeoff piece slot and fix the takeoff 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 force feeder

5.7.1 Mount the powder scrapper by tightening the screw at the rear side of the force feeder and tablet ejecting scrapper at the front side of the force feeder.

5.7.2 Mount the re-circular band on the turret.

5.7.3 Mount the force feeder on feeder support platform and clamp it in position with quick release clamp and tight the locking knobs.



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5.7.4 Check that an even clearance of approximately 0.12 mm (with the help of filler gauge) is maintained between die table and bottom surface of the force feeder.

5.7.5 Connect the feeder housing to feeder drive shaft by spring-loaded feeder coupling assembly.

5.7.6 Touch feeder jog switch on MMI and ensure the correct fitting of force feeder.

### 5.8 Fitting of hopper and connector:

5.8.1 Fit the hopper on its place by screwing the bolt at the top.

5.8.2 Fit the butterfly valve in the hopper connector to regulate the flow of powder.

5.8.3 Fit one end of hopper connector on the inlet pipe on the top of feeder bowls and the other end of the hopper connector to the hopper spout.

5.8.4 Fit the Tri clover clamp between the hopper connector and hopper spout to prevent disturbance of the connectors.

### 5.9 Setting of cam and dozer

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

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

### 5.10 Leveling of the Feeder Platform

5.10.1 To check the leveling place a parallel ground bar about 1" square and 10" long on the platform.

5.10.2 Check that the surface of the platform is perfectly parallel with the die table.

5.10.3 Use filler gauge to check that, the height of the platform must be 0.12 mm higher than the die table.

5.10.4 If height of the platform not found higher than 0.12 mm then adjust the platform, and again check with the filler gauge.

**Note:** If the clearance between the feeder platform and die table is more, there will more spillage of material from the space between the feeder and die table. If the clearance is less, bottom surface of the force feeder may be damaged.

### 5.11 Recipe Edit / Save / Delete

5.11.1 Turn 'ON' the mains. MMI will turn 'ON'. Opening screen will open.

5.11.2 Touch 'LOGIN' on the control panel. Security control screen will open.

5.11.3 Touch 'LOGIN' on MMI. Keypad will open. Enter the password in three different levels.



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5.11.4 Touch 'MAIN MENU' on MMI. Main menu screen will open with following menu:

- Machine Control      - Machine Status
- Turret control        - Recipe Management
- Feeder Control        - Batch Data
- Compaction force     - Technical data
- Lubrication Control - Security control

5.11.5 Touch 'RECIPE MANAGEMENT' on MMI. Recipe management screen will open.

5.11.6 Load product name, shape of tablet, size (Round / Other), thickness, weight, hardness, main tablet thickness (mm), compaction force (kN), Turret RPM, Depth of die fill, Tamping thickness, and main upper punch entry as per respective BMR.

5.11.7 Touch 'SAVE' on MMI. Keypad will open. Give suitable name / code for loaded recipe. For confirmation touch 'ENTER'. Recipe will save in PLC.

5.11.8 To load already exist recipe touch 'VIEW' on MMI. Loaded recipes list will open. Select the recipe and then touch 'ESC'. Warning message will appear. Touch 'YES'. Selected recipe will be loaded.

5.11.9 To delete recipe touch 'DELETE' on MMI. Loaded recipes list will open. Select the recipe and then touch 'ESC'. Warning message will appear. Touch 'YES'. Selected recipe will be deleted.

### 5.12 PLC Operation

5.12.1 Turn 'ON' the mains. Opening screen will open on MMI.

5.12.2 Touch 'LOGIN' on the control panel. Security control screen will open.

5.12.3 Touch 'LOGIN' on MMI. Keypad will open. Enter the password.

5.12.4 Touch 'MAIN MENU' on MMI. Main menu screen will open with following menu:

- Machine Control      - Machine Status
- Turret control        - Recipe Management
- Feeder Control        - Batch Data
- Compaction force     - Technical data
- Lubrication Control - Security control

5.12.5 Touch 'MACHINE STATUS' on MMI. Machine status-1 screen will open current status of following:

- Turret Motor Healthy                      - LH Feeder Motor Healthy
- RH Feeder Motor Healthy                   - LH Doser Assembly in Position
- RH Doser Assembly in Position           - Hydraulic Motor Healthy
- Lubrication Oil Level Healthy
- Emergency Push Button Released



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- 5.12.6 Touch 'MACHINE STATUS' on MMI. Machine status-2 screen will open current status of following:
- Machine Guard Closed
  - Batch Size Continuous
  - Guard Selection in interlock
  - Main Set Pressure Status (LH & RH) Healthy
  - Machine Selection Mode
  - Temping Pressure (LH & RH) Healthy
  - Tablet Counting Proxy in Posit
- 5.12.7 Touch "MAIN MENU" on MMI. Main menu screen will open.
- 5.12.8 Align vertical deduster next to the outlet chute of the compression machine and metal detector next to the outlet chute of the vertical deduster.
- 5.12.9 Place SS container lined with double polybag next to the metal detector outlet chute.
- 5.12.10 Load granules in the RHS and LHS hopper.
- 5.12.11 Turn 'ON' the compressed air supply. (to be deleted)
- 5.12.12 Touch on machine control, machine control screen will open on MMI.
- 5.12.13 Touch and hold 'JOG' on MMI on main drive sub screen. Machine will run till jog key is engage. Run the machine in jog mode and collect the compressed tablets on LHS and RHS station.
- 5.12.14 Check the weight then thickness and then hardness of individual tablet.
- 5.12.15 Ensure that weight, thickness and hardness of individual tablet is within limit specified in respective BMR. If not,
- 5.12.15.1 Set the weight by turning weight adjustment dial gauge in clockwise direction to increase the weight and anticlockwise direction to decrease the weight.
- 5.12.15.2 Set the thickness by turning tablet thickness controller in + direction to increase the thickness and reduce the hardness and in - direction to decrease the thickness and increase the hardness.
- 5.12.16 After setting weight and thickness, ensure friability and DT of the tablets are as per specification in respective BMR for LHS and RHS station.
- 5.12.17 Record all the observations in respective BMR.
- 5.12.18 Reject the tablets compressed during machine setting.
- 5.12.19 Operate the metal detector and vertical deduster.
- 5.12.20 Touch 'START' on MMI on main drive sub screen then touch 'CLUTCH ENGAGE' ON MMI on main drive sub screen clutch will engage. force feeder will start automatically machine will start running
- 5.12.21 To increase or decrease turret RPM touch '+ / -' on MMI on main drive sub screen.
- 5.12.22 To increase or decrease force feeder RPM touch '+ / -' on MMI on Feeder Control sub screen.
- 5.12.23 To increase or decrease compaction force touch '+ / -' on MMI on guards interlock sub screen.
- 5.12.24 Touch 'CLUTCH DISENGAGE' and then 'STOP' to stop the machine and turn 'OFF' mains and compressed air.



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### 5.13 Manual Operation

- 5.13.1 Turn 'ON' the mains. MMI will turn 'ON'. Select Bypass Mode.
- 5.13.2 Load the granules in LHS and RHS hooper. Set the vertical deduster and metal detector to the machine.
- 5.13.3 Press and hold 'JOG' key on control panel to run machine in jog mode.
- 5.13.4 Press 'START' button to run machine continuously.
- 5.13.5 Turn RPM knob clockwise to increase the turret RPM and anticlockwise to reduce the turret RPM.
- 5.13.6 Press green compaction force button to increase the compaction force and red button to decrease the compaction force.
- 5.13.7 Press 'STOP' button. Machine will stop. Turn 'OFF' mains and compressed air
- 5.13.8 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.
- 5.13.9 In case of "AUTO" mode failure during batch processing, machine can be run in "MANUAL" mode to Complete the batch by intimating to QA and Engineering department.

### 6.0 ABBREVIATION (S):

Q.A.	:	Quality Assurance
S.S.	:	Stainless Steel.
SOP	:	Standard operating procedure
IPA	:	Iso propyl alcohol
v/v	:	Volume/Volume
BMR	:	Batch manufacturing record
RPM	:	Rotations per Minute
mm	:	Millimeter
kN	:	Kilo Newton
MMI	:	Men machine interface
DT	:	Disintegration test
RHS	:	Right hand side
LHS	:	Left hand side





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### 7.0 REFERENCES (S):

SOP: Making entries in equipment usage and cleaning log sheet.

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:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (S):** Production department, Quality Assurance

9.3 **Reference Copy (S) :** Production department



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### ANNEXURE I

#### CLEANING CHECKLIST OF COMPRESSION MACHINE (55 STATION)

<b>Name of the Equipment</b>		<b>COMPRESSION MACHINE (55 STATION)</b>	
<b>Equipment ID No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

<b>S.No.</b>	<b>Activity</b>	<b>Activity performed</b>
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.	<b>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.</b>	
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.	
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.	



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S.No.	Activity	Activity performed
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 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.