



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of 51- 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 51-Station Double Rotary Compression machine.

### 2.0 SCOPE:

This SOP applicable to the Cleaning and Operation of 51-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:

**Change over from one batch to next batch of the same product, same potency and have similar product with ascending potency.**

5.1.1 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.

5.1.2 Ensure that the main power supply is put OFF and press the emergency switch.

5.1.3 Enter the cleaning start time in equipment usage log sheet as per SOP.

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 and from the machine carefully.

5.1.6 Dismantle carefully the following parts.

Feed hopper, Turret guards, Tablet collecting chutes, Upper & Lower punches.

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

5.1.8 Clean the machine feed hopper, turret guard, and 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 office/QA officer.



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- 5.1.10 Set the disassembled cleaned parts.
- 5.1.11 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine.
- 5.1.12 Enter the cleaning completion time in equipment usage log as per SOP.

### 5.2 "TYPE B" CLEANING

**This is a cleaning procedure for Changeover of product with different actives / color / descending potency or after maintenance of contact parts.**

- 5.2.1 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and Signature of the production officer.
- 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 hopper, rotary feeders, tablet discharge chutes, turret guards, suction nozzles, guide for excess powder, and upper guards for upper enclosure.
- 5.2.7 Dismantle the scrapper blade, ejection plate, re-circulating bend, feeder gaskets & feeder cover, Put all the dismantled parts in a virgin polybag affixed with "TO BE CLEANED" label and transfer the polybag to respective cleaning area.
- 5.2.8 Clean all the above parts first with 15-20 liters of purified water, then clean by using nylon scrubber and wash with 50-60 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 30-35 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 polybag 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 front and rare cover guards of the machine.
- 5.2.16 Remove the upper punches one by one and clean with a lint free cloth and keep in a tray.



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- 5.2.17 Remove anti- turning plugs and tension plate. Remove the plug by turning.
- 5.2.18 Remove the lower punches through the hole one by one, wipe to clean and keep in a SS trolley.
- 5.2.19 Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.
- 5.2.20 Smear of food grade oil on the punches and dies and store in the respective cabinet.
- 5.2.21 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.
- 5.2.22 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.
- 5.2.23 Remove all the dies in same manner and keep in a SS tray.
- 5.2.24 Clean with nylon brush dipped in 70% v/v IPA and dry with a cleaned lint free cloth.
- 5.2.25 Clean the upper and lower cam tracks with a lint free cloth dipped in 70% v/v IPA.
- 5.2.26 Clean the lower punch barrels using nylon brush dipped in 70% v/v IPA and then clean with a cleaned lint free cloth.
- 5.2.27 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.
- 5.2.28 Dry the die cavity and turret with a dry lint free cloth.
- 5.2.29 Clean the edge on the upper side of the lower guide holes. Clean the underside of the turret at the bottom of the lower guide holes a lint free cloth dipped in 70% v/v IPA.
- 5.2.30 Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.
- 5.2.31 Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.
- 5.2.32 Dry the pipe with the help of compressed air.
- 5.2.33 Fit the side covers of the compression machine back in place.
- 5.2.34 Replace the “TO BE CLEANED” status label with “CLEANED” status label with date and Signature of the production officer/QA officer.
- 5.2.35 Clean the area as per SOP.
- 5.2.36 Record the cleaning activity in equipment usage log as per SOP.
- 5.2.37 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.



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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.

5.3.3 Cleaning is applicable in case of at the end of working day, Dedusting of machine with vacuum cleaner and dry lint free clothe.

**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.

### 5.4.0 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 change part room and record the issuance in the Die Punches Utilization Record.

5.4.3 Clean the die and punch set with 70 % v/v IPA before installing on the compression machine.

### 5.5.0 Setting of round die punches:

5.5.1 Ensure the punch guide holes and die pockets are thoroughly cleaned.

5.5.2 Take the die and placed on the die table of the turret, by pressing the die down with the fingers. Once the die is located, the die driving bars entered through the upper punch guide hole and allowed to drop onto the die face three to four times from 3 to 4 inches height. When the die is fitted correctly, the top face must be perfectly flush with the turret, also check that after tightening the die screw.

5.5.3 Pull out the weight adjustment mechanism (RH) to load the lower punches.

5.5.4 Insert the lower punch into the guide hole, push to its highest position and ensure it drops freely under its own weight. Push the punch up and rotate the turret by hand wheel until the punch is clear of the loading port.

5.5.5 Fit the break plugs, which is tensioned by a leaf spring and positioned by a round head screw.

5.5.6 Place the upper punch in upper punch hole and check that punch is free to move in its guide hole.

5.5.7 Fit the remaining punches and dies in the same way.

### 5.6.0 Setting of other than round die punches:

5.6.1 Ensure the punch guide holes and die pockets are thoroughly cleaned.

5.6.2 Remove the piece of upper punch guide cam.



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- 5.6.3 Place the upper punch in upper punch hole and make sure that it will work up and down freely without any doubt of the tightness in the keyway. With the punch still in that position, place a die over the punch tip before entering the die into the die pocket and tap gently with the upper punch to position the die in the cavity.
- 5.6.4 Remove the upper punch and fix the dies in die cavity by using an Allen key.
- 5.6.5 When the die is fitted correctly, the top face must be perfectly flush with the turret, also check that after tightening the die screw.
- 5.6.6 Hold the upper punch up to the guide cam and turn the handle wheel, then rest the upper punch on the upper punch guide cam track.
- 5.6.7 Insert the lower punch into the guide hole, push to its highest position and ensure it drops freely under its own weight. Push the punch up and rotate the turret by hand wheel until the punch is clear of the loading port.
- 5.6.8 Fit the break plugs, which is tensioned by a leaf spring and positioned by a round head screw.
- 5.6.9 Place the upper punch in upper punch hole and check that punch is free to move in its guide hole.
- 5.6.10 Fit the remaining punches and dies in the same way.
- 5.7.0 Setting of force feeder:**
- 5.7.1 Clean the top surface of feeder support platform and bottom surface of the force feeder.
- 5.7.2 Mount the force feeder on the feeder support platform. Clamp it in position with quick release clamp and tighten the locking knob.
- 5.7.3 Connect the feeder housing to feeder drive shaft by inserting the spring-loaded feeder coupling assembly.
- 5.7.4 Scrapers are inserted in feeder housing and tail over die respectively and are spring-loaded.
- 5.7.5 Fit the guide for excess powder and take off plate.
- 5.7.6 Connect the feeder housing to feeder drive shaft by spring-loaded feeder coupling assembly.
- 5.7.7 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.
- 5.7.8 Touch feeder jog switch on HMI and ensure the correct fitting of force feeder.
- 5.8.0 Fitting of hopper and connector:**
- 5.8.1 Insert hopper from top of hood. Lags of hopper rest on studs lock it with nuts.
- 5.8.2 Position the butterfly valve at bottom of hopper, fit the triclover clamp.
- 5.8.3 Insert rubber below at bottom of butterfly valve and clamp it.
- 5.9.0 Leveling of the Feeder Platform:**



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- 5.9.1 To check the leveling place a parallel ground bar about 1” square and 10” long on the platform.
- 5.9.2 Check that the surface of the platform is perfectly parallel with the die table.
- 5.9.3 Use filler gauge to check that, the height of the platform must be 0.12 mm higher than the die table.
- 5.9.4 If height of the platform not found higher than 0.12 mm then adjust the platform, and again check with the filler gauge.

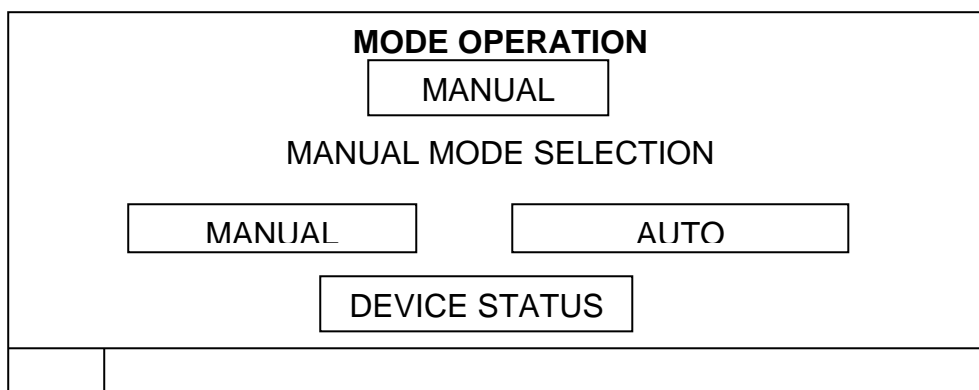
**Note:** If the clearance between the feeder platform and die table is more, there will more spillage of material from the space between the feeder and die table. If the clearance is less, bottom surface of the force feeder may be damaged.

### 5.10.0 Setting of cam and dozer:

- 5.10.1 Initially keep cam loose and after setting two or three die punches, fix the cam.
- 5.10.2 Ensure cam is not touching any part of machine and then fix the dozer.
- 5.10.3 The adjusting dial for tablet thickness (rare and front) and upper punch entry (rare and front) is located at the front of the machine as per direction arrow, from here adjust the thickness and punch entry manually.
- 5.10.4 The dial is rotated clockwise to increase thickness and vice versa.
- 5.10.5 Rotating the adjusting dial sited on the right and left sides of the machine varies the height of the weight adjusting head. The dial is rotated clockwise to increase filling depth and vise versa.

### 5.11.0 Machine operation:

- 5.11.1 After login, Mode Operation Screen shown below will prompt after touching Mode Operation button from Main menu screen.



- 5.11.2 Touch the appropriate button to perform the related operation.



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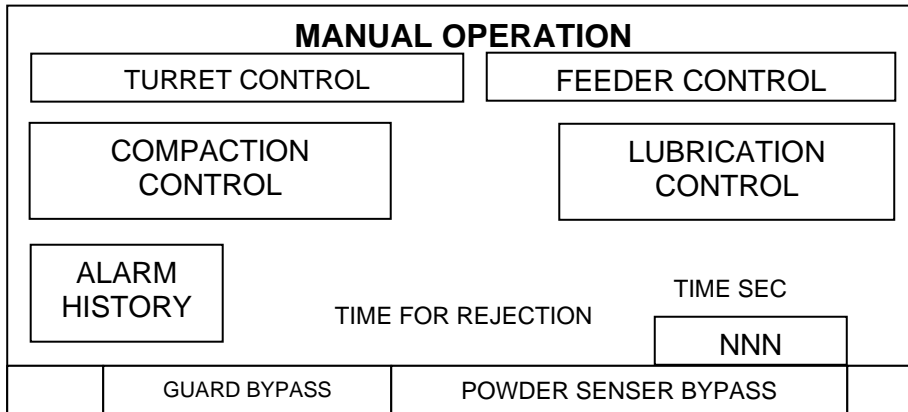
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### 5.11.3 MANUAL OPERATION:

Manual operation screen shown below will prompt after selecting and touching Manual button from Mode Operation button.



5.11.4 From here, we navigate turret control, feeder control, compaction control, and lubrication control.

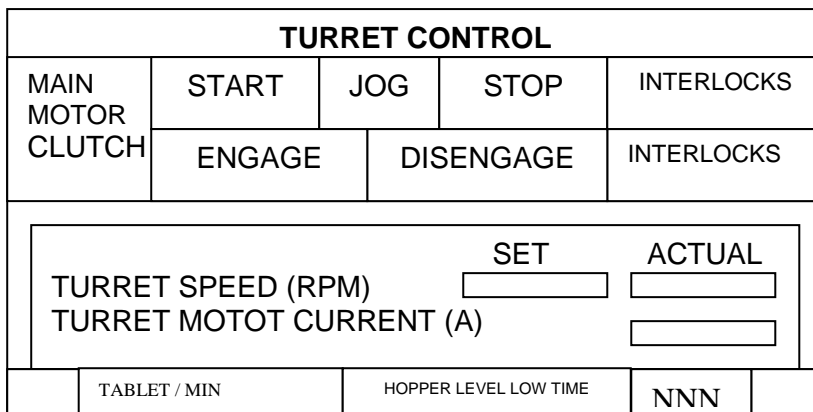
5.11.5 Put the machine guard and powder level, either in Interlock or in bypass mode.

5.11.6 Machine cannot run with guard Interlock condition and Powder level low condition after set value of Powder level time in turret control screen.

5.11.7 Initial rejection made starts automatically with machine start and stop till set value of time.

### 5.11.8 TURRET CONTROL:

Turret control screen shown below will prompt after Touching Turret control, from Manual Mode operation screen.



5.11.9 Set the Turret speed from 12 to 60 RPM, in set column. Actual RPM can be seen in actual column. Current drawn by the motor also seen in actual current column.



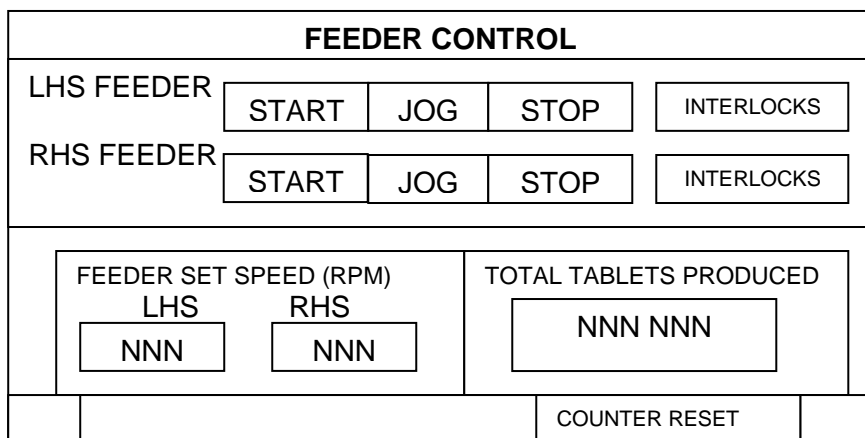
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- 5.11.10 Before start the machine ensures that turret motor and clutch, all interlocks mentioned in Interlock screen is healthy. Unhealthy interlocks will blink.
- 5.11.11 Turret motor starts and stops by touching 'START' and 'STOP' button. Turret also runs in jog mode by touching 'JOG' button.
- 5.11.12 Engage and Disengage the clutch to start and stop the turret by touching the 'ENGAGE' and 'DISENGAGE' buttons.
- 5.11.13 Set the powder level time to stop the turret after receiving powder level low alarm and completion of set value of powder level time.
- 5.11.14 **FEEDER CONTROL:**  
Feeder control screen shown below will prompt after touching Feeder control button from Manual operation.



- 5.11.15 Set the LHS and RHS feeder speed from 10 to 120 RPM in set column.
- 5.11.16 LHS and RHS feeder motor can be start, stop and jog by touching the START, STOP and JOG button respectively.
- 5.11.17 Total tablets produced till date seen in Total tablets set column.
- 5.11.18 **COMPACTION CONTROL:**  
Compaction control screen will prompt after touching compaction control button from Manual operation screen.
- 5.11.19 Increase or decrease the compaction by touching the INCREASE or DECREASE button.
- 5.11.20 **LUBRICATION CONTROL:**  
Lubrication control screen will prompt after touching Lubrication control button from Manual operation screen.
- 5.11.21 Lubrication can be start, stop and jog by touching the START, STOP and JOG button respectively.





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### 5.11.22 AUTO OPERATION:

Auto operation screen shown below will prompt after selecting and touching Auto button from Mode selection screen.

<b>AUTO OPERATION</b>		
[ AUTO CYCLE ]		
[ BATCH DATA ]		
[ RECIPE PARAMETERS ]		
	GUARD INTERLOCK	POWDER SENSOR INTERLOCK

5.11.23 For recipe touch the 'BATCH DATA' button from the Auto operation.

5.11.24 Here enter the Batch code, Product name, Operator name, and Batch size. Saved recipe selected from recipe no. Column. Selected recipe recalled by touching Recall button.

5.11.25 Before starting the machine Load that recall recipe.

5.11.26 Auto cycle screen shows below will prompt after touch Auto cycle button.

<b>AUTO CYCLE</b>			
[ START ]	[ JOG ]	[ STOP ]	
	SET	ACTUAL	
TURRET MOTOR CURRENT (A)		[ ]	
TURRET SPEED (RPM)	[ ]	[ ]	
LHS/RHS FEEDER RPM	[ ]	[ ]	[ ]

5.11.27 Put the machine guard and powder level, either in Interlock or in bypass mode.

5.11.28 Machine cannot run with guard Interlock condition and Powder level low condition after set value of Powder level time in turret control screen.

5.11.29 After selecting the recipe and touching download button from recipe screen, start the Auto cycle. Turret, Clutch, and both feeder will start as per the set speed. Set speed, actual turret RPM, and current shown in respective column.

**NOTE:** Before touching Start button to start Auto cycle, ensure that all interlocks mention in interlock screen must be healthy.

5.11.30 Ensure the setting of scarper is so that tablet should not break during initial machine setting.



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### 6.0 ABBREVIATION (S):

Q.A.	:	Quality Assurance
S.S.	:	Stainless Steel.
SOP	:	Standard operating procedure
No.	:	Number
IPA	:	Iso propyl alcohol
ml	:	Milliliter
v/v	:	Volume/Volume
BMR	:	Batch manufacturing record
RPM	:	Rotations per Minute
mm	:	Millimeter
kN	:	Kilo Newton
HMI	:	Human machine interface
DT	:	Disintegration test
RHS	:	Right hand side
LHS	:	Left hand side
R.H.	:	Relative humidity

### 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.

### 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 (51 STATION)

Name of the Equipment		COMPRESSION MACHINE (51 STATION)	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity performed	
1.	Ensure that the main power supply is put OFF and press the emergency switch.		
2.	Unscrew the panel covering on the front side and the side covers.		
3.	Dry clean the machine control panel from outside and inside using vacuum cleaner and with dry lint free cloth.		
4.	Clean beneath the compression machine and fit the panel covering back in place.		
5.	Dismantle the hopper, rotary feeders, tablet discharge chutes, turret guards, suction nozzles, guide for excess powder, and upper guards for upper enclosure.		
6.	Dismantle the scrapper blade, ejection plate, re-circulating bend, feeder gaskets & feeder cover, Put all the dismantled parts in a virgin polybag affixed with "TO BE CLEANED" label and transfer the polybag to respective cleaning area.		
7.	Clean all the above parts first with 15-20 liters of purified water, then clean by using nylon scrubber and wash with 50-60 liters of purified water.		
8.	Dismantle the feeder assembly including the acrylic plate and wash with purified water.		
9.	Finally rinse all the above washed parts with 30-35 liters of purified water.		
10.	Wipe all the cleaned parts with lint free cloth dipped in 70 % v/v IPA.		
11.	Dry all the parts using a dry lint free cloth.		
12.	Keep all the dried parts on a cleaned stainless steel pallet and cover it with a virgin polybag with a status label as "CLEANED" with date and signature of the production officer and transfer them to respective compression area.		
13.	Open the acrylic guard and clean with a dry lint free cloth.		
14.	Remove the front and rare cover guards of the machine.		
15.	Remove the upper punches one by one and clean with a lint free cloth and keep in a tray.		
16.	Remove anti- turning plugs and tension plate. Remove the plug by turning.		



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S.No.	Activity	Activity performed
17.	Remove the lower punches through the hole one by one, wipe to clean and keep in a SS trolley.	
18.	Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.	
19.	Smear of food grade oil on the punches and dies and store in the respective cabinet.	
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.	
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.	
22.	Remove all the dies in same manner and keep in a SS tray.	
23.	Clean with nylon brush dipped in 70% v/v IPA and dry with a cleaned lint free cloth.	
24.	Clean the upper and lower cam tracks with a lint free cloth dipped in 70% v/v IPA.	
25.	Clean the lower punch barrels using nylon brush dipped in 70% v/v IPA and then clean with a cleaned lint free cloth.	
26.	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.	
27.	Dry the die cavity and turret with a dry lint free cloth.	
28.	Clean the edge on the upper side of the lower guide holes. Clean the under side of the turret at the bottom of the lower guide holes a lint free cloth dipped in 70% v/v IPA.	
29.	Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.	
30.	Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.	
31.	Dry the pipe with the help of compressed air.	
32.	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.