



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of 37- Station Double Rotary Compression Machine	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 37-station double rotary Compression machine.

2.0 SCOPE:

- 2.1 This SOP applicable to the cleaning of 37-station double rotary compression machine 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 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.
- 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 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.



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

5.1.11 Replace the "UNDER CLEANING" status label with "CLEANED" status label with batch details of next batch details, date and signature of Production Officer and verified by QA Officer.

5.1.12 Enter the cleaning completion time in equipment usage log 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 Replace the "EQUIPMENT STATUS" status label with "UNDER CLEANING" 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 feed hopper view glasses, feeders, circulating arms, feed frame, upper punch guards, suction nozzles.

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 "UNDER CLEANING" 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 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)



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- 5.2.11 Finally rinse all the above washed parts with 20-25 liters of purified water.
- 5.2.12 Wipe all the cleaned parts with lint free cloth dipped in 70 % v/v IPA.
- 5.2.13 Dry all the parts using a dry lint free cloth.
- 5.2.14 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.
- 5.2.15 Open the acrylic guard and clean with a dry lint free cloth.
- 5.2.16 Remove the upper punches one by one and clean with a lint free cloth and keep in a tray.
- 5.2.17 Remove anti- turning plugs and tension plate.
- 5.2.18 Remove the plug by turning clockwise direction.
- 5.2.19 Remove the lower punches through the hole one by one, wipe to clean and keep in a SS tray.
- 5.2.20 Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.
- 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 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 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 Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.
- 5.2.30 Transfer the pipe to the washing area in a polythene bag and wash the inside of the pipe under a flow of purified water.
- 5.2.31 Dry the pipe with the help of compressed air.
- 5.2.32 Fit the side covers of the compression machine back in place.



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- 5.2.33 Inform the engineering department to clean the return air riser filter.
- 5.2.34 Replace the “UNDER CLEANING” 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 “CLEANING OF PRODUCTION AREA”.
- 5.2.36 Record the cleaning activity in equipment usage log as per SOP “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.
- 5.2.37 Record the cleaning checklist as per Annexure –I “Cleaning checklist of compression Machine (37 Station)”.

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 change over of product with different actives / colour / ascending potency / 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 (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 “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.

5.4 **Machine setting:**

- 5.4.1 Ensure that the equipment and area is cleaned and place ‘EQUIPMENT STATUS’ label duly filled and signed on the machine and record all the observations in equipment usage log as per SOP “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.
- 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 solution before installing on the compression machine.



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5.5 **Leveling of the Feeder Platform:**

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

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

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

5.5.4 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.

5.6 **Tablet take-off plate setting:**

5.6.1 At the time of setting of tablet take-off plate assembly, maintain the vertical gap of approx. 0.50 mm between the bottom edge of the tablet take off and turret die table.

5.6.2 The take-off plate must be adjusted in such a way that the tablet is completely ejected out of the die and smooth tablet take-off must take place.

5.7 **Setting of round die punches:**

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

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

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

5.7.4 Place upper punch in upper punch bores.

5.7.5 Turn the flywheel and set all die punches on compression machine by following step no. 5.5.1 to 5.5.4.

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

5.8 **Setting of other than round die punches:**

5.8.1 Fix the die in die cavity.



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- 5.8.2 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.
- 5.8.3 Ensure that the upper punch is freely moving in the respective die.
- 5.8.4 Remove the upper punch and fix the dies in die cavities by using a Tommy.
- 5.8.5 Ensure that the die is fixed at the same level with the turret.
- 5.8.6 Tighten the die locking screws. Cover the die locks with the SS cover provided.
- 5.8.7 Ensure that the upper punch is free in the respective die.
- 5.8.8 Remove the take off piece from the cam track.
- 5.8.9 Rest the upper punch on cam track. Turn the flywheel and set all the dies and punches in same fashion.
- 5.8.10 Remove the upper punch near the take off piece slot and fix the take off piece.
- 5.8.11 Place the upper punch back to the upper punch bore and tighten the punch locking screw.
- 5.8.12 Place lower punches in lower punch bores.
- 5.8.13 Fix the anti turning Teflon plugs by tightening the spring plates.
- 5.9 **Setting of force feeder:**
- 5.9.1 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.
- 5.9.2 Mount the re-circular band on the turret.
- 5.9.3 Mount the force feeder on feeder support platform and clamp it in position with quick release clamp and tight the locking knobs.
- 5.9.4 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.
- 5.9.5 Connect the feeder housing to feeder drive shaft by spring-loaded feeder coupling assembly.
- 5.9.6 Touch feeder jog switch on MMI and ensure the correct fitting of force feeder.
- 5.10 **Fitting of hopper and connector:**
- 5.10.1 Fit the hopper on its place by screwing the bolt at the top.
- 5.10.2 After fix the hopper screw tight the low powder level sensor to the hopper.
- 5.10.2 Fit the butterfly valve in the hopper connector to regulate the flow of powder.
- 5.10.3 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.



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5.10.4 Fit the triclover clamp between the hopper connector and hopper spout to prevent disturbance of the connectors.

5.11 **Setting of cam and dozer:**

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

5.11.2 Ensure cam is not touching any part of machine and then fix the doser.

5.12 **Recipe Edit / Save / Delete:**

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

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

5.12.6 Load product name, shape of tablet, size (Round / Other), thickness, weight, hardness, main tablet thickness (mm), compaction force (kN) as per respective BMR.

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

5.12.8 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.

5.12.9 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.

5.13 **PLC Operation:**

5.13.1 Turn 'ON' the mains and compressed air. Opening screen will open on MMI.

Note : Machine will not run if compressed air pressure is less than 3kg/cm²

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



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- 5.13.3 Touch 'LOGIN' on MMI. Keypad will open. Enter the password.
- 5.13.4 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
- 5.13.5 Touch 'MACHINE STATUS'- 1 on MMI. Machine status-1 screen will open current status of following:
- Turret Motor - LH Feeder Motor
 - RH Feeder Motor - LH Doser Assembly Position
 - RH Doser Assembly Position - Hydraulic Motor Status
 - Lubrication Oil Level - Air Pressure Status
 - Emergency Push Button- Machine Guard
- 5.13.6 Touch 'MACHINE STATUS' on MMI. Machine status-2 screen will open current status of following:
- Guard Selection - Batch Size Continuous
 - Machine Selection Mode - Main Set Pressure Status
 - Tablet Counting Proximity Switch Position
- 5.13.7 Touch "MAIN MENU" on MMI. Main menu screen will open.
- 5.13.8 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.
- 5.13.9 Place SS container lined with double polybag next to the metal detector outlet chute.
- 5.13.10 Load granules in the RHS and LHS hopper.
- 5.13.11 Turn 'ON' the compressed air supply.
- 5.13.12 Select 'TWO LAYER TABLET / STD. LAYER TABLET' as per respective BMR on MMI.
- 5.13.13 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.
- 5.13.14 Check the weight then thickness and then hardness of individual tablet.



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- 5.13.15 Ensure that weight, thickness and hardness of individual tablet is within limit specified in respective BMR. If not,
- 5.13.15.1 Set the weight by turning weight adjustment dial gauge in clockwise direction to increase the weight and anticlockwise direction to decrease the weight.
- 5.13.15.2 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.
- 5.13.16 After setting weight and thickness, ensure friability and DT of the tablets are as per specification in respective BMR for LHS and RHS station.
- 5.13.17 After setting of all the parameters, run the machine.
- 5.13.18 At the time running of bi layer tablets, for sampling of 1st layer of the bi layer tablet press the “SAMPLING OFF” on the PLC, it turn “SAMPLING ON”.
- 5.13.19 Collect the sample as required and then press the “SAMPLING ON”. Sampling of 1st layer off.
- 5.13.20 Record all the observations in respective BMR.
- 5.13.21 Reject the tablets compressed during machine setting.
- 5.13.22 Operate the metal detector and vertical de-duster.
- 5.13.23 Touch ‘CLUTCH ENGAGE’ on MMI on main drive sub screen. Clutch will engage. Force feeder will start automatically. Then touch ‘START’ on MMI on main drive sub screen. Machine will start running.
- 5.13.24 To increase or decrease turret RPM touch ‘+ / -’ on MMI on main drive sub screen.
- 5.13.25 To increase or decrease force feeder RPM touch ‘+ / -’ on MMI on Feeder Control sub screen.
- 5.13.26 To increase or decrease compaction force touch ‘+ / -’ on MMI on guards interlock sub screen.
- 5.13.27 Touch ‘CLUTCH DISENGAGE’ and then ‘STOP’ to stop the machine and turn ‘OFF’ mains and compressed air.
- 5.14 **Manual Operation**
- 5.14.1 Turn ‘ON’ the mains and compressed air. MMI will turn ‘ON’. Select Bypass Mode.
Note : Machine will not run if compressed air pressure is less than 4kg/cm²
- 5.14.2 Load the granules in LHS and RHS hopper. Set the vertical de-duster and metal detector to the machine.
- 5.14.3 Press and hold ‘JOG’ key on control panel to run machine in jog mode.



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- 5.14.4 Press 'START' button to run machine continuously.
- 5.14.5 Turn RPM knob clockwise to increase the turret RPM and anticlockwise to reduce the turret RPM.
- 5.14.6 Press green compaction force button to increase the compaction force and red button to decrease the compaction force.
- 5.14.7 During compression of batch, when powder level become low at the hopper from the low powder sensor. The machine shall be stop. Turn 'OFF' mains and compressed air.
- 5.14.8 Left over powder from feed frame and hopper (below low level sensor), shall be destroyed as per SOP (Disposal in production department).
- 5.14.9 At the end of operation affix 'UNDER CLEANING' label duly filled and signed on the machine and record all the observation in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".
- 5.14.10 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. Ensure the setting of scrapper is so that tablet should not break during initial machine setting.
- 5.14.11 **Note:** First two round tablets shall be destroy at every startup of compression machine.

6.0 ABBREVIATION (S):

- 6.1 Q.A. : Quality Assurance
- 6.2 S.S. : Stainless Steel.
- 6.3 SOP : Standard operating procedure
- 6.4 No. : Number
- 6.5 IPA : Iso propyl alcohol
- 6.6 ml : Milliliter
- 6.7 v/v : Volume/Volume
- 6.8 BMR : Batch manufacturing record
- 6.9 RPM : Rotations per Minute
- 6.10 mm : Millimeter
- 6.11 kN : Kilo Newton



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- 6.12 MMI : Men machine interface
6.13 DT : Disintegration test
6.14 RHS : Right hand side
6.15 LHS : Left hand side

7.0 REFERENCES (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
7.2 SOP: Issuance, use and retrieval of punches and dies.
7.3 SOP: Cleaning of Production Area.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Cleaning checklist of compression Machine (37 Station)		Log Book

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 department (01)

10.0 REVISION HISTORY:

S. No.	Version No.	Change Control No.	Reason (s) for revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA



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Annexure – I

Cleaning Checklist of Compression Machine (37 Station)

Name of the Equipment		Compression Machine (37 Station)	
Equipment ID No.		Previous product	
Batch No.		Date	

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 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)	
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.	
8.	Dismantle the feeder assembly including the acrylic plate and wash with purified water.	
9.	Finally rinse all the above washed parts with 20-25 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 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.	
13.	Open the acrylic guard and clean with a dry lint free cloth.	
14.	Remove the upper punches one by one and clean with a lint free cloth and keep its in a tray.	



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S.No.	Activity	Activity performed
15.	Remove the anti- turning plugs and tension plate.	
16.	Remove the plug by turning clockwise direction.	
17.	Remove the lower punches through the hole one by one, wipe to clean and keep in a SS tray.	
18.	Remove the adhered powder in the lower punch barrels and bottom of dies with a nylon brush.	
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.	
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.	
21.	Remove all the dies and keep in a SS tray.	
22.	Clean with nylon brush dipped in 70%v/v IPA and dry with a cleaned lint free cloth.	
23.	Remove the upper and lower cam tracks and clean it with a lint free cloth dipped in 70%v/v IPA.	
24.	Clean the lower punch barrels using nylon brush dipped in 70%v/v IPA and then clean with a cleaned lint free cloth.	
25.	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.	
26.	Dry the die cavity and turret with a dry lint free cloth.	
27.	Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water.	
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.	
29.	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.