



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of 45 station Compression Machine (Cadpress D Tooling)	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE :

To lay down a procedure for Cleaning of 45 station Compression Machine (Cadpress D Tooling).

2.0 SCOPE :

This procedure is applicable for cleaning of 45 station Compression Machine (Cadpress D Tooling) located in compression area in

3.0 RESPONSIBILITY:

Production: Technical Associate/Officer /Executive/Assistant Manager.
Head Production: To ensure execution & compliance.
Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Cleaning TYPE A :

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

- 4.1.1 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.
- 4.1.2 First check the hopper emptiness and filling chute.
- 4.1.3 Switch OFF the main electric supply to the machine.
- 4.1.4 Ensure that no compressed tablet remains in de-duster unit.
- 4.1.5 Remove “ TO BE CLEANED ” label and affix “ UNDER CLEANING ” label to the machine as per SOP.
- 4.1.6 Dismantle carefully the following parts: Powder level sensor, Hopper, Force feeder, Turret guard, Tablet collecting chutes.
- 4.1.7 Remove the powder from the above parts and machine with the help of dust collector hose or vacuum cleaner and clean the all above thoroughly with dry lint free cloth.



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4.1.8 Clean upper punches one by one along with dust cap with dry lint free cloth.

4.1.9 After completion of cleaning process, get it checked by production officer.

Remove the “UNDER CLEANING ” label and affix “CLEANED” label to the Machine and Enter the cleaning time in equipment sequential log as per SOP.

4.2 TYPE B:

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

4.2.1 First check the hopper emptiness and filling chute.

4.2.2 Release the hydraulic pressure from the pressure rollers.

4.2.3 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and Signature of the production officer.

4.2.4 Switch OFF the main electric supply to the machine.

4.2.5 Unscrew the panel covering on the front side and the side covers and clean with IPA soaked cloth and dry it with dry lint free cloth.

4.2.6 Dry clean the machine control panel from outside and inside using dust collector hose or vacuum cleaner and with dry lint free cloth. Clean beneath the compression machine and fit the panel covering back in place.

4.2.7 Dismantle the powder level sensors from hopper view glasses. butter fly valve, acrylic guard, upper punch guards, remove the Y-chute, hopper, hopper to feeder connector, force feeder, discharge chute, weight adjustment assembly, suction nozzles, the scrapper blade, ejection plate, re-circulating blade, feeder gaskets & feeder cover.

4.2.8 Transfer all the change parts like Y-chute, hopper, feeder connector, force feeder ,discharge chute, suction nozzle, scrapper blade ,ejection plate, re-circulating blade, acrylic guards, punch guards, lower cam guards etc to the washing area with the change parts trolley, affix “TO BE CLEANED” Label properly.

4.2.9 Clean all the change parts with a jet of approximate 20-30 Kg of purified water then clean by using nylon scrubber and wash with approximate 10-20 Kg of purified water. Finally rinse with approximate 5-10 Kg of purified water.



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- 4.2.10 Wipe all the cleaned parts with lint free cloth dipped in 70 % IPA and Dry all the parts using compressed air followed by dry lint free cloth.
- 4.2.11 Change Part Trolley Cleaning Procedure-
After cleaning of all dismantled parts, clean the change part trolley with a jet of approximate 10-20 Kg of purified water and finally rinse it with approximate 5-10 Kg of purified water.
- 4.2.12 Dry the change part trolley with dry lint free cloth or with compressed air.
Then transfer the cleaned part to it and close the doors and transfer it to compression cubicle.
- 4.2.13 Remove dust cap of respective upper punch one by one and clean each with purified water then IPA soaked cloth and dry with dry lint free cloth.
- 4.2.14 Remove upper punch one by one punch and clean each with IPA soaked cloth followed by dry lint free cloth and put them horizontally on die-punch handling tray duly labeled with details of punch specifications and their quantities.
- 4.2.15 Remove anti- turning plugs and tension plate and lower punches from the punch guiding - hole one by one, wipe to clean and keep in punch trolley.
- 4.2.16 Remove the adhered powder in the lower punch barrels and bottom of dies clean with dry lint free cloth.
- 4.2.17 Clean the upper punch, lower punch pocket and dies cavity using a dry nylon brush first then clean with a nylon brush dipped in 70% IPA and dry the punch pocket using a cleaned lint free cloth.
- 4.2.18 Remove the upper and lower cam tracks and clean it with a lint free cloth dipped in 70 % IPA.
- 4.2.19 Clean the lower punch barrels using lint free cloth dipped in 70% IPA.
- 4.2.20 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% IPA.
- 4.2.21 Dry the die cavity and turret with a dry lint free cloth.
- 4.2.22 Wipe the outside of the pipe of the dust extractor with a lint free cloth dipped in purified water, transfer the pipe to the washing area in a polythene bag , wash the inside of the pipe under a flow of approximate 20-30 Kg of purified water.



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- 4.2.23 Dry the pipe with the help of compressed air.
- 4.2.24 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.
- 4.2.25 Fit the side covers of the compression machine back in place.
- 4.2.26 Open the acrylic guard and remove the upper punches one by one and clean with a lint free cloth and keep it in a tray.
- 4.2.27 Inform the engineering department to clean the return air riser filter.
- 4.2.28 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and Signature of the production officer.
- 4.2.29 Record the cleaning activity in equipment sequential log as per SOP.
- 4.2.30 Fill the cleaning checklist duly sign by the technician and concerned officer as per annexure –I.
- 4.2.31 Note: During cleaning of punches and dies, visual check for any damage of punches and dies.
- 4.2.32 Clean the area as per SOP.

5.0 ANNEXURE (S):
Annexure –I: Cleaning checklist of Compression Machine (45 station D-Tooling).

6.0 REFERENCE (S):
SOP: Preparation, approval, Distribution control, Revision and destruction of Standard Operating Procedure (SOP).
SOP: Procedure for area line clearance.
SOP: Status labeling in production department.
SOP: Cleaning and Sanitization of Production Area.

7.0 ABBREVIATION (S) /DEFINITION (S):



PHARMA DEVILS

PRODUCTION DEPARTMENT

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BMR : Batch Manufacturing Record

Q.A. : Quality Assurance

SOP : Standard Operating Procedure

S.S : Stainless Steel

IPA : Isopropyl Alcohol

REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---