



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

|  |                        |
|--|------------------------|
| <b>Department:</b> Production                    | <b>SOP No.:</b>        |
| <b>Title:</b> Cleaning and Operation of Extruder | <b>Effective Date:</b> |
| <b>Supersedes:</b> Nil                           | <b>Review Date:</b>    |
| <b>Issue Date:</b>                               | <b>Page No.:</b>       |

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for cleaning and operation of Extruder.

### 2.0 SCOPE

2.1 This procedure is applicable to the cleaning and operation of Extruder in the production area.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate : Operation

3.2 Officer/ Executive Production : Supervision

3.3 Head Production : SOP Compliance

3.4 IPQA : Line Clearance

### 4.0 DEFINITION(S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 "TYPE A" CLEANING;

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

5.1.1 Ensure that all the materials of previous batch are removed from the Roll Compactor Area.

5.1.2 Ensure that main power supply is switched off.

5.1.3 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP (Status Labeling).

Record the cleaning start time in equipment usage log sheet equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.4 Dismantle the cutter, Clamp, cover plate, die roller, Knurling roller, extrusion hopper and discharge chute.

5.1.5 Clean the dismantled parts with a dry lint free duster.

5.1.6 Scrub the die roller & Knurling roller with a nylon scrubber to remove the adhered materials.

5.1.7 Assemble the dismantled part of the Extruder.

Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine. Record the cleaning end time in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

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



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### 5.2 “TYPE B” CLEANING:

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

- 5.2.1 Affix dully filled “TO BE CLEANED” status label on equipment with date and signature of the Production Officer as per SOP (Status Labeling).
  - 5.2.2 Ensure that the power supply is put off.
  - 5.2.3 Dismantle the cutter, Clamp, cover plate, die roller, Knurling roller, extrusion hopper and discharge chute.
  - 5.2.4 Clean the dismantled parts of the extruder using 4-6 liter of purified water with nylon scrubber in washing area.
  - 5.2.5 Clean all the above parts with 20-25 liters of purified water.
  - 5.2.6 Clean the roller by using purified water and with a nylon scrubber.
  - 5.2.7 Apply a jet of purified water so as to insure the complete removal of traces of the previous product. Clean the die roller & knurling roller and the extrusion assembly with 30-40 liter of purified water.
  - 5.2.8 Clean the outside bodies of extruder with help of lint free duster dip in purified water.
  - 5.2.9 Dry the cleaned parts by using compressed air.
  - 5.2.10 Dry all the dismantled parts and the body with the help of dry lint free cloth.
  - 5.2.11 Wipe all dismantled parts of the Extruder and its body with 70% v/v IPA solution.
  - 5.2.12 Certify the cleanliness by Production Officer and QA officer.
  - 5.2.13 Assemble the Extruder die roller& Knurling roller.
  - 5.2.14 Affix a label on Extruder as “CLEANED” with date and signature of the Production Officer and QA officer.
  - 5.2.15 If the Extruder is idle for 72 hours or more, then wipe all the parts of the Extruder with 70% v/v IPA solution before use.
  - 5.2.16 Cleaning activity checked and verified in Annexure-I (Cleaning checklist of Extruder Format”).
  - 5.2.17 Enter cleaning activity in ‘CLEANED” label.  
Record the cleaning completion activity of Extruder in equipment usage logbook as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.3 Clean the area as per SOP (Cleaning of production area).

### 5.4 Frequency:

- 5.4.1 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.
- 5.4.2 Type ‘B’ cleaning is applicable in case of changeover 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.



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5.4.3 Cleaning is applicable in case of at the end of working day, dedusting 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. If the machine is idle for 72 hours to 240 hours after B type cleaning, then wipe with 70% v/v IPA solution with the help of a lint free cloth and update the CLEANED status label with current date before use. If expire the cleaning validity (240 hrs or 10 days) after type B cleaning then type B cleaning shall be performed before use. Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

### 5.5 OPERATING PROCEDURE

5.5.1 Ensure the area and equipment is clean. Affix ‘EQUIPMENT STATUS’ label duly filled and signed on the machine and record all the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

#### 5.5.2 Machine setting

5.4.2.1 Product name dedicated die rollers and knurling rollers should be used for machine setting.

5.4.2.2 Issuance and return record should be updated before taking Die and Knurling rollers for machine setting Annexure-II (Issuance and Retrieval Record of Rollers Format).

5.4.2.3 Ensure that the main switch is in “OFF” position before setting of Extruder.

5.4.2.4 Ensure that the Extruder is cleaned and ready for use.

5.4.2.5 Fix the die roller in the extrusion assembly body.

5.4.2.6 Set the knurling roller in the extrusion assembly body.

5.4.2.7 Fix the cover plate and lock it with the clamp.

5.4.2.8 Set the cutter and lock the cover plate.

5.4.2.9 Adjust the speed (RPM) mentioned in the BMR by rotating the knob clockwise or anticlockwise.

5.4.2.10 Set the discharge chute.

5.4.2.11 Fix the extrusion hopper.

#### 5.5.3 Operation

After line clearance from Q.A., put the ‘EQUIPMENT STATUS’ label on the machine. Enter start time of the machine in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.4.3.1 Switch “ON” the mains from electrical panel.

5.4.3.2 Put the wet mass in extrusion hopper.



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- 5.4.3.3 Switch "ON" the electric supply and operate the toggle switch on control panel to start the operation of the machine.
- 5.4.3.4 Adjust the cutter with the help of adjustment bolt as per requirement of extrudate size.
- 5.4.3.5 Collect the extruded material into the cleaned S.S. container and then start for further processing as per BMR.
- 5.4.3.6 After completion of operation, stop the machine with the help of toggle switch provided on control panel.
- 5.4.3.7 Enter the completion time in equipment usage log sheet.

### 5.5.4 Precaution and check points:

- 5.4.4.1 Ensure that the cutter do not rub with the die roller.
- 5.4.4.2 Do not put oil in main motor shaft housing from inside.
- 5.4.4.3 Ensure that no over feeding to the hopper of the Extruder.

### 6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 v/v : Volume by Volume

### 7.0 REFERENCES(S):

- 7.1 SOP No.: Cleaning of production area.
- 7.2 SOP No.: Making entries in equipment usage and cleaning log sheet.
- 7.3 SOP No.: Status Labeling

### 8.0 ANNEXURE(S):

| Annexure no. | Title of Annexure                        | Format no. | Mode of Execution |
|--------------|--|------------|-------------------|
| Annexure I   | Cleaning checklist of Extruder           |            | Log Book          |
| Annexure II  | Issuance and Retrieval Record of Rollers |            | Log Book          |

### 9.0 DISTRIBUTION:

- 9.1 Master Copy : Quality Assurance
- 9.2 Controlled copy (S) : Production department (2)
- 9.3 Reference copy (S) : Production department (2)



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### 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 EXTRUDER

|                              |  |                         |  |
|------------------------------|--|-------------------------|--|
| <b>Name of the Equipment</b> |  | <b>Extruder</b>         |  |
| <b>Equipment I.D. No.</b>    |  | <b>Previous product</b> |  |
| <b>Batch No.</b>             |  | <b>Date</b>             |  |

| S.No. | Activity  | Activity Performed |
|-------|---|--------------------|
| 1     | Ensure that the power supply are put off.   |                    |
| 2     | Dismantle the cutter, Clamp, cover plate, die roller, Knurling roller, extrusion hopper and discharge chute.  |                    |
| 3     | Clean the dismantled parts of the extruder using 4-6 liter of purified water with nylon scrubber in washing area.   |                    |
| 4     | Clean all the above parts with 20-25 liters of purified water.  |                    |
| 5     | Clean the roller by using purified water and with a nylon scrubber.   |                    |
| 6     | Apply a jet of purified water so as to insure the complete removal of traces of the previous product. Clean the die roller & knurling roller and the extrusion assembly with 30-40 liter of purified water. |                    |
| 7     | Clean the outside body of extruder with help of lint free duster deeded in water.   |                    |
| 8     | Dry the cleaned parts by using compressed air.  |                    |
| 9     | Dry all the dismantled parts and the body with the help of dry lint free cloth.   |                    |
| 10    | Wipe all dismantled parts of the Extruder and its body with 70% v/v IPA solution.   |                    |

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

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

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

