



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Cleaning and Operation of Automatic Tablet/Capsule Printing Machine | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of Automatic Tablet/Capsule Printing Machine.

2.0 SCOPE:

This procedure is applicable to the cleaning and operation of Automatic Tablet/Capsule Printing Machine in the production area.

3.0 RESPONSIBILITY:

Technical Associate : Operation
Officer/ Executive Production : Supervision
Head Production : SOP Compliance
IPQA : 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 and same potency and of similar product with ascending potency.

- 5.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine.
- 5.1.2 Ensure that the main power supply is switched off on control panel & also check "OFF" position of emergency switch.
- 5.1.3 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.4 Record the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.5 Dismantle the cutter, cover plate, die roller, Knurling roller and discharge chute.
- 5.1.6 Lift up the upper window and side window for cleaning the feed disc assembly.
- 5.1.7 Clean the feed disc with the help of dry lint free cloth.
- 5.1.8 Clean the top plate, bowl, and center adjusting plate with dry lint free cloth.
- 5.1.9 Clean gravure roller and offset roll thoroughly with lint free cloth dipped in 70% IPA.
- 5.1.10 Remove the rejection bin and clean with dry lint free cloth.
- 5.1.11 Fixed the parts of printing machine.
- 5.1.12 Clean the outer surface of machine with dry lint free cloth.



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- 5.1.13 Production officer shall check the cleanliness.
- 5.1.14 Remove the "TO BE CLEANED" label and affix a label on equipments as "CLEANED" with date and signature of the Production Officer and QA officer.
- 5.1.14 Record the cleaning end time in the equipment usage log sheet as per SOP. After completion of cleaning process, get it checked by production officer.

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.
- 5.2.2 Ensure that the main power supply is switched off on control panel & also check "OFF" position of emergency switch.
- 5.2.3 Lift up the upper window and side window for opening and cleaning of feed disc assembly.
- 5.2.4 Open the handle and then lift up feed disc pressure plate, feed disc, and support disc with the help of plate handle.
- 5.2.5 Also dismantle side guide-1 and side guide-2, hopper, tablet arrestor, side support hopper, and special washer, and center adjusting plate, brush and rejection bin.
- 5.2.6 Clean all above dismantle parts with 30 to 40 liters of purified water and with the help of nylon scrubber in washing area.
- 5.2.7 Further clean all parts with 35 to 45 liter of purified water.
- 5.2.8 Remove inkpot ink (Start machine without object feed) and then clean the gravure and off set rolls thoroughly with 70% v/v IPA.
- 5.2.9 Finally rinse all the cleaned parts with the 15-20 liters of purified water.
- 5.2.10 Inspect rollers thoroughly.
- 5.2.11 Clean the inkpot assembly with the help of purified water followed by 70% v/v IPA. Ensure complete removal of ink from reservoir.
- 5.2.12 Fit the support disc with the help of plate handle and adjust the feed disc pressure plate and feed disc.
- 5.2.13 Fit the side guide-1 and side guide-2, hopper, tablet arrestor, side support hopper, special washer, and center adjusting plate, brush and rejection bin.
- 5.2.14 Affix a label on printing machine as "CLEANED" with date and signature of the Production Officer.
- 5.2.15 Replace the "TO BE CLEANED" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.



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5.2.16 Record the cleaning completion time in equipment usage log sheet as per SOP.

5.2.17 Clean the area as per SOP.

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 / 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.

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 OPERATING PROCEDURE:

5.4.1 Ensure that the equipment is cleaned.

5.4.2 After line clearance from QA, put the "UNDER PROCESS" label on the machine.

5.4.3 Enter start time of the machine in equipment usage log sheet as per SOP.

5.4.4 Switch ON the mains from the electric panel board.

5.4.5 Ensure that the emergency switch is release on control panel of machine then start machine by pressing the "green" button on control panel.

5.4.6 Set the speed of the feed disc with the help of "Speed ADJ." Switch on control panel.

5.4.7 Press the green button switch to run the 'feed disc' and to stop the 'feed disc', press 'red' button present on control panel.

5.4.8 Set the gravure as per product requirement.

5.4.9 Set inkpot assembly with its reservoir (with required ink).

5.4.10 Operate the printing machine in jog mode during setting of printing quality.

5.4.11 Load the tablet/capsule in hopper and print a few Tablet/capsule to check whether the prints are in center (If required set printing by timing pulley screw and nut). Also set printing center by adjusting side printing assembly position by the help of alignment wheel.(Set as printing come in center of tablet)

5.4.12 Set pressure of off set roller for clear visibility.

5.4.13 After getting required printing start machine in Auto mode by operating toggle switch towards 'Auto' direction on control panel.

5.4.14 Collect the printed tablets/Capsules into a container lined with double polythene bags near discharge.

5.4.15 Ensure that the compressed air supply is regular NLT 4 kg/cm² throughout the operation.



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5.4.16 After completion of activity, switch “OFF “the machine by pressing “RED” button from control panel.

5.4.17 Enter end time of the machine in equipment usage log sheet as per SOP.

5.5 Precautions:

5.5.1 Keep bowl supplied with product.

5.5.2 Keep inkpot full during operation.

5.5.3 Inspect prints as per requirement (or as per BMR).

5.5.4 Clean rolls as per necessary (Stop feed with air ejector during roller cleaning).

5.5.5 Always set product printing in “jog” mode.

6.0 ABBREVIATION (S):

IPA : Iso Propyl Alcohol

SOP : Standard Operating Procedure

v/v : Volume by Volume

QA : Quality Assurance

7.0 REFERENCES(S):

SOP: Cleaning of production area.

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

SOP: Status Labeling

8.0 ANNEXURE(S):

Annexure I : Cleaning checklist of Automatic Tablet / Capsule Printing Machine

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 AUTOMATIC TABLET/CAPSULE PRINTING MACHINE

Name of the Equipment: Automatic Tablet/Capsule Printing Machine

Previous product:

Equipment ID No.:

Batch No. :

Date:

| S.No. | Activity | Activity Performed |
|-------|--|--------------------|
| 1. | Ensure that the main power supply is switched off on control panel & also check "OFF" position of emergency switch. | |
| 2. | Lift up the upper window and side window for opening and cleaning of feed disc assembly. | |
| 3. | Open the handle and then lift up feed disc pressure plate, feed disc, and support disc with the help of plate handle. | |
| 4. | Also dismantle side guide-1 and side guide-2, hopper, tablet arrestor, side support hopper, special washer, and center adjusting plate, brush and rejection bin. | |
| 5. | Clean all above dismantle parts with 30 to 40 liters of purified water and with the help of nylon scrubber in washing area. | |
| 6. | Further clean all parts with 35 to 45 liter of purified water. | |
| 7. | Remove inkpot ink (Start machine without object feed) and then clean the gravure and off set rolls thoroughly with 70% v/v IPA. | |
| 8. | Finally rinse all the cleaned parts with the 15-20 liters of purified water. | |
| 9. | Inspect rollers thoroughly. | |
| 10. | Clean the inkpot assembly with the help of purified water followed by 70% v/v IPA. Ensure complete removal of ink from reservoir. | |
| 11. | Fit the support disc with the help of plate handle and adjust the feed disc pressure plate and feed disc. | |
| 12. | Fit the side guide-1 and side guide-2, hopper, tablet arrestor, side support hopper, special washer, and center adjusting plate, brush and rejection bin. | |

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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