



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Tablet Counter Machine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning and Operation of Tablet Counter Machine.

2.0 SCOPE:

This procedure is applicable to the cleaning and operation of Tablet Counter Machine in production area.

3.0 RESPONSIBILITY:

Technical Associate: Cleaning and Operation

Officer and Executive: Supervision

Head Production: SOP compliance

IPQA Person: Line Clearance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 CLEANING:

This is a cleaning procedure applicable for cleaning after completion of every batch/or any maintenance activity.

- 5.1.1 Ensure that the tablet counter machine is switched off.
- 5.1.2 Replace "UNDER PROCESS" label with "TO BE CLEANED" status label with date and signature of production officer.
- 5.1.3 Dry clean the tablet counter machine body, control panel and utility cables using a dry lint free duster.
- 5.1.4 Remove the hopper and clean it by using a dry lint free duster.
- 5.1.5 Remove the vibration plate by unscrewing the bolts. Clean the inner part of the powder collection port by using dry lint free duster.
- 5.1.6 Clean the tablet rotating disc and outer side of machine by using dry lint free duster.
- 5.1.7 Wipe the all the dismantled parts of machine with 70% v/v IPA followed by clean dry lint free cloth.
- 5.1.8 Assemble the dismantled parts of the Tablet Counter Machine.
- 5.1.9 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of production officer.
- 5.1.10 If the same product is proceeds for more than one week, then follow the procedure of cleaning as per SOP.
- 5.1.11 Record the cleaning activity in equipment usage log book as per SOP.



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5.1.12 Cleaning is idle for 72 hours, if machine is not used with in 72 hours clean the machine “before use” with lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and mention the 70% v/v IPA cleaning on the previous “CLEANED” label attached on the machine. And record the activity in equipment usage log sheet as per SOP.

5.2 PRECAUTIONS:

5.2.1 Don't keep the excess tablets in rotating plate.

5.3 OPERATION:

- 5.3.1 Replace “CLEANED” label with “UNDER PROCESS” status label with date and signature of Production Officer.
- 5.3.2 Enter the start time in the equipment usage log sheet as per SOP.
- 5.3.3 Switch “ON” the mains from electrical panel.
- 5.3.4 Adjust batch counter to fill the required quantity of tablets in container/Triple laminated pouch.
- 5.3.5 Adjust the width of deflector according to the size of tablet by putting a tablet in to the guide.
- 5.3.6 Adjust tablet deflector with bottom gap allowing only one tablet to pack.
- 5.3.7 Adjust outlet of guide set to middle of photocell so that the tablet can be correct counted.
- 5.3.8 Pour the tablets in to the hopper.
- 5.3.9 Turn rotary adjuster and vibrant speed adjuster to zero.
- 5.3.10 Keep two containers/ triple laminated pouches properly under discharge chute.
- 5.3.11 Turn the rotary adjuster to adjust the speed 2.0 to 6.0.
- 5.3.12 Adjust the feeding gate to proper position.
- 5.3.13 Turn the vibrant speed adjuster to proper feeding speed.
- 5.3.14 Transfer the tablets from container to LDPE polybag / triple laminated bag and pack as per BPR.
- 5.3.15 After completion of batch enter the completion time in the equipment usage log sheet as per SOP.
- 5.4.16 Put the “TO BE CLEANED” label dully filled and signed with production officer.

6.0 ABBREVIATION (S):

QA : Quality Assurance

SOP : Standard Operating Procedure

v/v : Volume/Volume

LDPE : Low Density Polyethylene



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7.0 RERERENCE (S):

Nil

8.0 ANNEXURE (S):

Nil

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

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