



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning & Operation of Bulk Counter Machine (Make: Parle Global Technology)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for cleaning & operation of Bulk Counter Machine (Parle Global Technology Ltd.)

2.0 SCOPE:

This procedure is applicable for cleaning & operation of Bulk Counter Machine in production department.

3.0 RESPONSIBILITY:

Technical Associate: Operation

Officer/ Executive Production/IPQA: Supervision

Head Production: SOP Compliance.

IPQA: SOP Compliance.

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 CLEANING:

5.1.1 TYPE A:

This is a cleaning procedure for changeover of one batch to next batch of same product and same potency.

5.1.1.1 Ensure that the power supply and compress air supply is switched "OFF".

5.1.1.2 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and signature of production officer.

5.1.1.3 Clean the Tablet counter machine body, control panel and utility cables using a dry lint free cloth.

5.1.1.4 Remove the disc supporter and nylon brush and clean with dry lint free cloth.

5.1.1.5 Remove the tablet rotating disc by unscrewing bolts. Clean the inner supporting base part of the rotating disc by using dry lint free cloth.

5.1.1.6 Remove the tablet discharge chute and clean by using dry lint free cloth.

5.1.1.7 Assemble the dismantled parts of the Tablet counter machine.

5.1.1.8 Replace 'TO BE CLEANED' status label with "CLEANED" status label with date and signature of the Production Officer.



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5.1.1.9 Record the cleaning activity in equipment usage log book as per SOP.

5.1.2 TYPE B:

This is a cleaning procedure for change over of product with different actives/colour/descending potency/ascending potency or after maintenance.

5.1.2.1 Ensure that the power supply and compress air supply is switched 'OFF'.

5.1.2.2 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and signature of production officer.

5.1.2.3 Clean the control panel, machine body and utility cables using a dry lint free cloth.

5.1.2.4 Dismantle disc supporter, nylon brush, center plate, tablet rotating disc, tablet discharge chute, powder collection pipe, dedust with lint free cloth and put all the parts in a virgin poly bag and take them to washing area.

5.1.2.5 Clean the inside portion of the powder collection pipe with a nylon brush dipped in purified water and dry the parts using compressed air followed dry lint free cloth.

5.1.2.6 Flush the dismantled parts with purified water sufficient to remove the powder and to remove the adhered particulate scrub the parts with nylon brush using the purified water.

NOTE: 2% Sodium Lauryl Sulphate (SLS) solution shall be used for scrubbing by nylon brush if API is Efavirenz before final rinsing of equipment/parts.

5.1.2.7 Finally rinse the cleaned parts with the 40-50 liters of purified water.

5.1.2.8 Dry the dismantled parts using dry lint free cloth.

5.1.2.9 Wipe the dismantled parts with lint free cloth using 70 % v/v IPA solution followed by mopping with dry lint free cloth.

5.1.2.10 Clean the supporting base of rotating disc and surface of the machine with a lint free cloth dipped in 70% v/v IPA solution.

5.1.2.11 Replace 'TO BE CLEANED' status label with "CLEANED" status label with date and signature of the Production Officer.

5.1.2.12 If the machine is idle for 72 hours after cleaning, re-clean by mopping with 70% v/v IPA solution by using lint free cloth before use.

5.1.2.13 Sign the previous 'CLEANED' status label with the current date with date and signature of the Production Officer.

5.1.2.14 Record the cleaning activity in equipment usage log book as per SOP.

5.2 MACHINE SETTING:

5.2.1 Replace the "CLEANED" status label with "UNDER PROCESS" status label with date and signature of production officer.



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- 5.2.2 Switch "ON" the mains from electrical panel.
- 5.2.3 Adjust Tablet counter machine to fill the required quantity of tablets in container/Triple laminate pouch.
- 5.2.4 Fit the product specific tablet rotating disc on the machine.
- 5.2.5 Adjust the setting of the nylon brush to remove extra tablet from the pocket of the rotating disc.
- 5.2.6 Adjust the level of the discharge chute of tablet counter machine as per size of the container/Triple laminated pouch.

5.3 OPERATING PROCEDURE:

- 5.3.1 Feed the tablet into tablet rotating disc.
- 5.3.2 Keep container/ Triple laminate pouch properly under discharge chute.
- 5.3.3 Turn the rotary adjuster to proper speed.
- 5.3.4 Enter the completion time in the equipment usage log sheet as per SOP.

6.0 ABBREVIATION (S):

SOP: Standard Operating Procedure.

No. : Number

SLS : Sodium Lauryl Sulphate

7.0 REFERENCE(S):

SOP: Status labeling

SOP: Making entries in equipment usage and cleaning log sheet

SOP: Production area cleaning.

8.0 ANNEXURE (S):

ANNEXURE I- Cleaning checklist of Tablet counter machine

9.0 DISTRIBUTION (S):

Master copy : Quality Assurance

Controlled copy (s) : Production department, Quality Assurance

Reference copy (s) : Production department



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ANNEXURE I

CLEANING CHECKLIST OF TABLET COUNTER MACHINE (Parle Global Technology Ltd.)

Name of the Equipment	Tablet counter machine		
Equipment ID. No.		Previous Product	
Batch No.		Date	

S.No.	Activity	Activity Performed
1.	Ensure that the power supply and compress air supply to machine is disconnected "OFF".	
2.	Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and signature of production officer.	
3.	Clean the control panel, machine surface and utility cables by using lint free cloth.	
4.	Dismantle disc supporter, nylon brush, center plate, tablet rotating disc, tablet discharge chute, powder collection pipe, de-dust with lint free cloth and put all the parts in a virgin poly bag and take them to washing area.	
5.	Clean the inside portion of the powder collection pipe with a nylon brush dipped in purified water and dry the parts using compressed air followed dry lint free cloth.	
6.	Flush the dismantled parts with purified water sufficient to remove powder. To remove the adhered particulate scrub the parts with nylon brush using purified water. NOTE: 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.	
7.	Finally rinse the cleaned parts with the 40-50 liters of purified water.	
8.	Wipe the dismantled parts using dry lint free cloth.	
9.	Wipe all the dismantled parts with lint free cloth using 70% v/v IPA solution.	
10.	Clean the supporting base of rotating disc and surface of the machine with a lint free cloth using 70% v/v IPA solution followed by mopping with lint free cloth.	
11.	Replace the 'TO BE CLEANED' status label by 'CLEANED' status label with sign and date of production officer.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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