



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Tablet Loader 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 Loader Machine.

2.0 SCOPE:

This procedure is applicable to Cleaning and Operation of Tablet Loader machine located in manufacturing 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 "TYPE-A" CLEANING: This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.

5.1.1 Put "OFF" the main switch of the Tablet Loader machine.

5.1.2 Ensure that no IPC bin are present on the machine.

5.1.3 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine as per SOP.

5.1.4 Enter the cleaning start time in equipment usage log sheet SOP.

5.1.5 Dismantle the chute by opening the clamp.

5.1.6 Remove the powder deposited on machine by using lint free cloth.

5.1.7 Clean the chute using lint free cloth

5.1.8 Clean the control panel with dry lint free cloth.

5.1.9 After cleaning affix "CLEANED" label as per SOP.

5.2 "TYPE B" CLEANING: This is cleaning procedure for changeover of product with different activity / color / descending potency/ascending potency or after maintenance of contact parts.



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- 5.2.1 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.
- 5.2.2 Enter the cleaning start time in equipment usage log sheet SOP.
- 5.2.3 Follow the same procedure from step no 5.1.5 to 5.1.7.
- 5.2.4 Dismantle the chute by opening the clamp.
- 5.2.5 Clean the arm and body with dry lint free cloth followed by wet lint free cloth.
- 5.2.6 Clean the chute with 20 to 25 liters of purified water using lint free cloth.
- 5.2.7 Rinse the chute with 5 to 10 liters of purified water.
- 5.2.8 Clean the cleaned chute with 2% sodium lauryl Sulphate before final rinsing in case of API is Efavirenz.
- 5.2.9 Wipe with dry lint free cloth to remove water followed by wipe with lint free cloth dipped in 70% IPA.
- 5.2.10 Clean the control panel with dry lint free cloth.
- 5.2.11 After cleaning affix "CLEANED" label and transfer to cleaned area.

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 7 days then follow the procedure of type - B cleaning as per SOP.
- 5.3.2 Type B cleaning is applicable in case of changeover of product with different actives/color /descending/ascending potency or after maintenance of contact parts or same product is run for more than seven days type -B cleaning done after completion of batch as per SOP.
- 5.3.3 Cleaning is applicable in case of at the end of working day, De-dusting of machine with dry 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 cloth dipped in 70% v/v IPA solution followed by dry lint free duster and affix the dully signed "CLEANED" label. Record the activity in equipment usage log sheet as per SOP.

5.4 Operation:

5.4.1 Loading of IPC Bins:

- 5.4.1.1 Turn "ON" the mains of Tablet Loader machine.
- 5.4.1.2 Lock the PU wheel of IPC bin.
- 5.4.1.3 Level the height of Tablet loader machine arm to the height of IPC bin arm by using "UP (YELLOW) / DOWN (BLUE)" push button on main.
- 5.4.1.4 Insert the Tablet Loader machine arm inside the IPC bin arm, and then lock both the arm of tablet loader machine with the help of locking pins.



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5.4.1.5 Uplift the Tablet loading machine by pressing “**Yellow**” push button and connect the tablet transfer “Chute” to the bottom of IPC bin and tight the chute using TC clamp.

5.4.1.6 Adjust the height of tablet loader machine by pressing “**UP (YELLOW) / DOWN (BLUE)**” push button and put the opening of tablet transfer chute inside the coating pan.

5.4.1.7 Open the butterfly valve of IPC bin and unload the tablets in coating pan.

5.4.1.8 Repeat the step no.: 5.4.1.1 to 5.4.1.7 for rest of IPC bins of the Batch / Lot.

5.4.2 **Unloading of IPC Bin:**

5.4.2.1 Close the butterfly valve of IPC bin and disconnect the tablet transfer chute by losing the TC clamp.

5.4.2.2 Down the IPC bin by pressing “**DOWN (BLUE)**” push button on main.

5.4.2.3 Open the lid of IPC bin and check for any tablet inside, if any then transfer to coating pan.

5.4.2.4 Unload the IPC bin on the floor by using “**DOWN (BLUE)**” push bottom on main.

5.4.2.5 Unlock the IPC bin by removing the locking pin from both arm of tablet loader machine.

5.4.2.6 Pull back manually the tablet loader machine to De-attach the IPC bin and transfer the empty IPC bin for cleaning.

5.4.2.7 Repeat the step no.: 5.4.2.1 to 5.4.2.6 for rest of the IPC bins of the Batch / Lot.

5.5 **Precaution:**

5.5.1 Before uplifting the loaded IPC bin ensure the proper locking of bin arms.

5.5.2 Lock the PU wheel of tablet loader machine during loading and unloading of IPC bins.

5.5.3 Before open the butterfly valve of IPC bin check that the discharged port of tablet transfer chute is properly inserted inside the coating pan.

5.5.4 Ensure no tablets are damaged during loading.

6.0 **ABBREVIATION (S):**

SOP : Standard Operating Procedure

IPC : In process Product Container

IPA : Iso Propyl Alcohol

PU : Poly Urethane



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7.0 REFERENCES (S):

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

SOP: Status labeling.

8.0 ANNEXURE (S):

Annexure-I: Cleaning Checklist of Tablet Loader 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 LOADER MACHINE

Name of the Equipment		TABLET LOADER	
Equipment I.D. No.		Previous product	
Batch No.		Date	
S.No.	Activity		Activity performed
1.	Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.		
2.	Enter the cleaning start time in equipment usage log sheet SOP.		
3.	Dismantle the chute by opening the clamp.		
4.	Remove the powder deposited on machine by using lint free cloth.		
5.	Clean the chute using lint free cloth		
6.	Clean the arm and body with dry lint free cloth followed by wet lint free cloth.		
7.	Clean the chute with 20 to 25 liters of purified water using lint free cloth.		
8.	Rinse the chute with 5 to 10 liters of purified water.		
9.	Wipe with dry lint free cloth to remove water followed by wipe with lint free cloth dipped in 70% IPA.		
10.	Clean the control panel with dry lint free cloth.		
11.	After cleaning affix "CLEANED" label and transfer to cleaned area.		

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date