



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Tipper	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Tipper.

2.0 SCOPE:

2.1 The procedure is applicable to the Cleaning and Operation of Tipper in production department.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation of Tipper

3.2 Officer/ Executive Production: Supervision of Cleaning and Operation of Tipper

3.3 Head Production : SOP Compliance

3.4 IPQA : SOP Compliance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

At the end of shift, change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the color is same.

5.1.1 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP "STATUS LABELING".

5.1.2 Ensure that power supply is turned "OFF".

5.1.3 Clean the tipper cone with lint free cloth.

5.1.4 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer/QA officer as per SOP "STATUS LABELING".

5.1.5 Clean the area as per SOP "CLEANING OF PRODUCTION AREA".

5.1.6 Record the cleaning activity in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

5.2 "TYPE B" CLEANING:

During changeover of product with different actives / color / descending potency or after maintenance of contact parts.



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- 5.2.1 Follow the step no. 5.1.1 to 5.1.3.
- 5.2.2 Cover the control panel and gear box with polybag to avoid water entry in to them.
- 5.2.3 Dedust the equipment with dry lint free cloth.
- 5.2.4 Wash the inner and outer surface of tipper bowl with nylon scrubber to remove the adhere material.
- 5.2.5 Wash the inner and outer surface of tipper bowl with 30 -40 liters of purified water to remove the residue of previous product.
- 5.2.6 Scrub the inner and outer surface of tipper bowl with nylon scrubber to remove the adhere material.
- 5.2.7 Remove the screws of pneumatic butterfly valve and clean with dry lint free duster.
- 5.2.8 Wash and scrub the pneumatic butterfly valve with 5 liters of purified water to remove the adhere material.
- 5.2.9 Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)
- 5.2.10 Finally rinse the tipper inner and outer surface and pneumatic butterfly valve with 30-40 liters of purified water.
- 5.2.11 Wipe the tipper inner and outer surface and pneumatic butterfly valve of tipper bowl with dry lint free cloth.
- 5.2.12 Wipe the tipper inner and outer surface and pneumatic butterfly valve of tipper bowl with 70% v/v IPA solution.
- 5.2.13 Ensure that the area is cleaned as per SOP "CLEANING OF PRODUCTION AREA".
- 5.2.14 Record the cleaning activity end time of machine in equipment usage log as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".
- 5.2.15 Affix 'CLEANED' label on equipment with date and signature of the Production Officer/QA officer as per SOP "STATUS LABELING".
- 5.2.16 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP "STATUS LABELING".
- 5.2.17 Ensure that the area is cleaned as per SOP "CLEANING OF PRODUCTION AREA".
- 5.2.18 Record the cleaning activity of equipment in equipment usage log as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".



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5.3 **FREQUENCY:**

- 5.3.1 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.
- 5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / color / 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.
- 5.3.3 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. Record the activity in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

5.4 **OPERATION:**

- 5.4.1 Ensure "CLEANED" label is dully filled and signed is affixed on the equipment.
- 5.4.2 Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "EQUIPMENT STATUS" label dully filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".
- 5.4.3 Switch 'ON' the mains (on main panel) and then switch 'ON' control panel 'ON/OFF' Key (on control panel).
- 5.4.4 Bring the FBD bowl trolley perfectly blow inverted tipper cone when the tipper cone is at the bottom most position.
- 5.4.5 Clamp the tipper cone and FBD bowl assembly using Rotate 0-180° push button till the tipper cone positions perpendicular above the sifter/sifter cum multi mill.
- 5.4.6 For charging the material to the sifter/sifter cum multi mill ensure that the equipment's charging hopper is properly below the butterfly valve of the tipper cone.
- 5.4.7 Open the butterfly valve of the tipper cone to the below placed charging hopper of the equipment by putting time for opening and delay of pneumatic butterfly valve.
- 5.4.8 After the operation is over, remove the below kept equipment from the tipper cone.



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- 5.4.9 Invert the tipper cone and FBD bowl assembly using “Rotate 180-0°” push button after bringing it to the desired height.
- 5.4.10 Bring the FBD trolley below the tipper cone and FBD bowl and lower the assembly till the FBD bowl resets on the FBD bowl trolley.
- 5.4.11 Unlock the tipper cone and FBD bowl assembly and remove the FBD bowl with trolley for cleaning.
- 5.4.12 Remove and destroy “EQUIPMENT STATUS” label and affix “UNDER CLEANING” label dully filled and signed by production officer on the equipment as per SOP “STATUS LABELING”.

6.0 ABBREVIATION (S):

- 6.1 Lts. : Liters
- 6.2 IPA : Iso Propyl Alcohol
- 6.3 v/v : Volume/ Volume
- 6.4 BMR : Batch Manufacturing Record
- 6.5 SLS : Sodium Lauryl Sulphate

7.0 REFERENCES (S):

- 7.1 SOP: Cleaning of production area.
- 7.2 SOP: Making entries in equipment usage and cleaning log sheet
- 7.3 SOP: Status Labeling

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Cleaning Checklist of Tipper		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S):** Production department (01), QA department (01)
- 9.3 **Reference copy (S) :** Production department (01)

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 TIPPER

Name of the Equipment		Tipper	
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1	Ensure that power supply is turned "OFF".	
2	Clean the tipper cone with lint free cloth.	
3	Wash the inner and outer surface of tipper bowl with nylon scrubber to remove the adhere material.	
4	Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)	
5	Wash the inner and outer surface of tipper bowl with 30 - 40 liters of purified water to remove the residue of previous product.	
6	Scrub the inner and outer surface of tipper bowl with nylon scrubber to remove the adhere material.	
7	Remove the screws of pneumatic butterfly valve and clean with dry lint free duster.	
8	Wash and scrub the pneumatic butterfly valve with 5 liters of purified water to remove the adhere material.	
9	Finally rinse the tipper inner and outer surface and pneumatic butterfly valve with 30-40 liters of purified water.	
10	Wipe the tipper inner and outer surface and pneumatic butterfly valve of tipper bowl with dry lint free cloth.	
11	Wipe the tipper inner and outer surface and pneumatic butterfly valve of tipper bowl with 70% v/v IPA solution.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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