



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Pneumatic Conveying System	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 Pneumatic Conveying System.

2.0 SCOPE:

2.1 This procedure is applicable to the cleaning and Operation procedure of pneumatic conveying system in the production area.

3.0 RESPONSIBILITY:

3.1 Technical Associate: Cleaning and Operation of pneumatic conveying system

3.2 Production Officer/Executive: Checking Cleaning and Operation of pneumatic conveying system

3.3 Head Production: SOP Compliance of Cleaning and Operation of pneumatic conveying system

3.4 IPQA Person: Line clearance and verification Cleaning and Operation of pneumatic conveying system

4.0 DEFINITION (S):

4.1 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 “EQUIPMENT STATUS” label and affix dully filled “UNDER CLEANING” label to the machine.

5.1.2 Enter the cleaning start time equipment usage and cleaning log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.1.3 Ensure that the main power supply is switched “OFF”.

5.1.4 Open the clamp of vacuum receiver assembly then collect and remove if any residue of previous product present in filter.

5.1.5 Clean the inner and outer side of the vacuum receiver assembly with the help of dry lint free duster.

5.1.6 **Cleaning procedure for Pull and Drop System:**

5.1.6.1 Follow the same procedure from 5.1.1 to 5.1.3.



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- 5.1.6.2 Disconnect the electrical connections of Pull and Drop System.
- 5.1.6.3 Dismantle the opening lid of Pull and Drop system by losing the tightening nuts.
- 5.1.6.4 Dismantle the filter bag assembly.
- 5.1.6.5 Clean all the dismantle parts with dry lint free duster till visually clean.
- 5.1.6.6 Clean and remove if any residue of previous product present in filter.
- 5.1.6.7 Clean the lid with lint free cloth.
- 5.1.6.8 Clean the inner and outer side of the Pull and drop system with the help of dry lint free duster.
- 5.1.6.9 Clean the product hose pipes with dry lint free cloth.
- 5.1.7 Again assemble the filter and close the clamp of Pull and drop system.
- 5.1.8 Affix dully filled status label on pneumatic conveying system as "CLEANED" with date and signature of Production Officer verified by QA officer.
- 5.1.9 Record the cleaning completion time in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").
- 5.2 **"TYPE B" CLEANING: This is a cleaning procedure for Changeover of product with different Actives/Color/Descending Potency or after Maintenance of contact parts.**
 - 5.2.1 Switch off the main power supply.
 - 5.2.2 Remove "EQUIPMENT STATUS" label and affix dully filled "UNDER CLEANING" label to the machine.
 - 5.2.3 Enter the cleaning start time in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").
 - 5.2.4 Open the clamp of hose pipe and vacuum receiver.
 - 5.2.5 Dismantle the SS cage and filter bag.
 - 5.2.6 Clean the filter bag and SS cage with 30-35 liters of purified water using nylon scrubber.
 - 5.2.7 Dry the filter bag in FBD with finger bag (At 65 °C temperature until the out let temperature is achieved 63 °C to 65 °C.).
 - 5.2.8 Clean the hose pipe with flush of 50-60 liters purified water.
 - 5.2.9 Clean SS vacuum line all clamps and stand of vacuum receiver with using lint free cloth dipped in purified water and followed by dry lint free cloth.
 - 5.2.10 Clean control panel with dry lint free cloth.
 - 5.2.11 **Cleaning procedure for Pull and Drop System:**
 - 5.2.11.1 Follow the same procedure from step no. 5.2.1 to 5.2.3.



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- 5.2.11.2 Dismantle the electrical connections of Pull and Drop System & wrap with clean polybag to avoid the entrance of water in electrical connections.
- 5.2.11.3 Dismantle the opening lid of pull and drop System by loosening the tightening nuts.
- 5.2.11.4 Dismantle the filter bag assembly.
- 5.2.11.5 Clean all the dismantled parts and bag housing with 20-25 liters of purified water and nylon scrubber.
- 5.2.11.6 Clean the filter bag with 25-30 liters of purified water using nylon scrubber till visually clean.
- 5.2.11.7 Dry the filter bag in FBD with finger bag (At 65 °C temperature until the out let temperature is achieved 63 °C to 65 °C).
- 5.2.11.8 Clean the product hose pipes with 50-60 liters of Purified water using nylon scrubber.
- 5.2.12 Clean the cleaned parts with 2% w/v Sodium Lauryl sulfate (For 1 liter 2% w/v Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.
- 5.2.13 After cleaning with 2% w/v sodium Lauryl sulfate clean the parts with 30-35 liters of purified water.
- 5.2.14 Ensure that area is cleaned as per SOP (“Cleaning of Production Area”).
- 5.2.15 Wipe out the all part of vacuum receiver, vacuum line and pull and drop system with a clean dry lint free duster and finally wipe with 70% v/v IPA solution.
- 5.2.16 Replace the “UNDER CLEANING” status label with the “CLEANED” status label with date and signature of Production Officer and QA Officer.
- 5.2.17 Record the cleaning completion time in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).
- 5.2.18 Record the cleaning activity in Annexure – I “Cleaning checklist for Pneumatic Conveying System”.
- 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 seven days then follow the procedure of Type – ‘B’ cleaning as per SOP (“Cleaning verification”).
- 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



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seven days cleaning Type - B done after completion of batch as per SOP (“Cleaning verification”).

5.3.3 Cleaning is applicable in case of at the end of working day, de dusting of machine with vacuum cleaner or with lint free cloth.

NOTE:

1. 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”).
2. Filter bag cleaning and utilization record is to be updated in Annexure-II “PCS filter bag cleaning and utilization record”.
3. Filter bag inventory record is to be updated on receipt of new filter bag and destruction of old filter bag in Annexure-III “PCS filter bag inventory record”.

5.4 OPERATION:

5.4.1 Machine Assembling:

5.4.1.1 Product Conveying System:

5.4.1.1.1 Ensure that the equipment and area is cleaned. Affix ‘EQUIPMENT STATUS’ label dully filled and signed on the equipment and record the observation in the Equipment Usage Log Sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.4.1.1.2 Fit the product dedicated filter bag with SS cage of Vacuum receiver and tight the claps.

5.4.1.1.3 Tight the clamp of bag chamber with vacuum receiver.

5.4.1.1.4 Connect the one end of the hose pipe with vacuum receiver and second end with Octagonal Blender/Bin Blender/IPC and tight properly with SS clamps.

5.4.1.1.5 Ensure all seal, gaskets, hose pipe, and clamps are fitted properly.

5.4.1.2 Pull and Drop System:

5.4.1.2.1 Follow the same procedure from 5.4.1.1.1 to 5.4.1.1.3.

5.4.1.2.2 Connect the one end of latex sleeve with discharge chute of Pull and Drop System and second end with Octagonal Blender/Bin Blender/IPC and tight properly.

5.4.2 Machine Operation:

5.4.2.1 Product Conveying System:



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- 5.4.2.1.1 Turn “ON” the main power supply switch.
- 5.4.2.1.2 Turn “ON” the control button.
- 5.4.2.1.3 Press the “MENU” button on HMI.
- 5.4.2.1.4 Login to the system with password, after login following settings will appear:
1. “0” number indicates discharge Timer
 2. “1” number indicates purging Timer
 3. “2” number indicates vacuum Timer
- 5.4.2.1.5 By using the “SCROLL” button and “A” button set the timings.
- 5.4.2.1.6 Now press Menu Button display will show “TIME SEQUENCE 12”.
- 5.4.2.1.7 Press “START” button to start the operation.
- 5.4.2.1.8 After completion of the operation press stop button and turn of the control and main power button.
- 5.4.2.2 **Pull and Drop System:**
- 5.4.2.2.1 Turn “ON” the main power supply switch.
- 5.4.2.2.2 Turn “ON” the control button.
- 5.4.2.2.3 Press the “MENU” button on HMI.
- 5.4.2.2.4 Login to the system with password, after login use green colored keys for settings of material hold timer in LHS of control panel:
1. “1” number indicates to enter the set time count
 2. “2” number indicates to change the count format
 3. “3” number indicates to increase or decrease the time count
 4. “4” number indicates to reset the timer
- 5.4.2.2.5 Same green colored keys used for settings of material discharge timer in RHS of control panel, given in step no. 5.4.2.2.4.
- 5.4.2.2.6 Press “START” button to start the operation.
- 5.4.2.2.7 After completion of the operation press “STOP” button and turn of the control and main power button.
- 5.4.3 **PRECAUTIONS:**
- 5.4.3.1 Ensure that all the hose pipe connections are tightly closed.
- 5.4.3.2 Always use the product dedicate filter bags in Vacuum receiver.

6.0 ABBREVIATION (S):



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- 6.1 IPA : Isopropyl Alcohol
- 6.2 PCS : Pneumatic Conveying System
- 6.3 HMI : Human Machine Interface.

7.0 REFERENCE (S):

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

8.0 ANNEXURE (S)

Annexure no.	Title of Annexure	Format No.	Mode of execution
Annexure-I	Cleaning checklist for Pneumatic Conveying System		Logbook
Annexure-II	PCS filter bag cleaning and utilization record		Logbook
Annexure-III	PCS filter bag inventory record		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S)** : Production department (01), Quality Assurance
- 9.3 **Reference Copy (S)** : Production department (05)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
01	00		New SOP	NA	



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ANNEXURE I

CLEANING CHECKLIST OF PNEUMATIC CONVEYING SYSTEM

Name of the Equipment		Pneumatic Conveying System	
Equipment I.D. No.:		Previous product	
Batch No.		Date	

S.No.	Activity	Activity Performed
1.	Switch off the main power supply.	
2.	Open the clamp of hose pipe and vacuum receiver.	
3.	Dismantle the SS cage and filter bag.	
4.	Clean the filter bag and SS cage with 30-35 liters of purified water using nylon scrubber.	
5.	Clean SS vacuum line all clamps and stand of vacuum receiver with using lint free cloth dipped in purified water and followed by dry lint free cloth	
6.	Clean all the dismantle parts and bag housing with 20-25 liters of purified water and nylon scrubber	
7.	Clean the filter bag with 25-30 liters of purified water using nylon scrubber till visually clean.	
8.	Clean the product hose pipes with 50-60 liters of Purified water using nylon scrubber.	
9.	Clean the cleaned parts with 2% Sodium Lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.	
10.	After cleaning with 2% sodium Lauryl sulfate clean the parts with 30-35 liters of purified water	
11.	Clean SS vacuum line all clamps and stand of vacuum receiver with purified water using lint free cloth.	
12.	Clean control panel with dry lint free cloth.	
13.	Wipe out the all part of vacuum receiver, vacuum line with a clean dry lint free duster and finally Wipe with 70%v/v IPA.	

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

Checked By (Prod.)
(Sign/date)

Verified By (QA)
(Sign/date)

