



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of Vacuum Tray Dryer.

2.0 SCOPE:

The procedure is applicable for the cleaning and operation of Vacuum Tray Dryer in production department.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation
Production Officer/ Executive : Checking of Cleaning and Operation
IPQA Person : Line Clearance, On line Process Confirmation.
Head Production : SOP Compliance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the colour is same.

- 5.1.1 Ensure that power supply is turned "OFF".
- 5.1.2 Remove and destroy "TO BE CLEANED" label.
- 5.1.3 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.4 Remove all trays from the drier and keep on SS pallet.
- 5.1.5 Drain the accumulated water from the "Moisture content Reservoir".
- 5.1.6 Remove the adhered materials from the trays by using dry lint free cloth.
- 5.1.7 Clean all the internal parts such as convection plate and inner SS walls of the equipment with a dry lint free cloth.
- 5.1.8 If the same product is processed for more than a week, then follow the procedure of cleaning as followed during product change over as per Type B cleaning.
- 5.1.9 Affix duly filled and signed "CLEANED" label on the equipment.
- 5.1.10 Record the cleaning completion time in the equipment usage log sheet as per SOP.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2 “TYPE B” CLEANING:

During change over of product with different actives /colour/descending potency or after maintenance of contact parts.

- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.4.
- 5.2.2 Cover the electric panel with the polybags.
- 5.2.3 Clean the trays with 40 to 45 liters of purified water by using nylon scrubber.
- 5.2.4 Wash the trays with 35 to 40 liters of purified water.
- 5.2.5 Rinse the trays with 15 to 20 liters of purified water
- 5.2.6 Clean the internal parts like convection plate and inner SS walls by using CIP pump and Finally rinse the Vacuum Tray Dryer with the 50-60 liters of purified water and remove the water droplets through compressed air.
- 5.2.7 Run the vacuum tray dryer for 10 minutes to remove internal moisture.
- 5.2.8 Clean outer parts such as body, vacuum releasing chamber, hot water supply and return pipe and door of the equipment with a lint free cloth dipped in purified water.
- 5.2.9 Clean the electric panel with dry lint free cloth.
- 5.2.10 Wipe the all parts with 70 % v/v IPA solution.
- 5.2.11 In case equipment remains idle for 72 hours, re-clean the equipment by wiping with 70 % v/v IPA solution before use.
- 5.2.12 Affix duly filled and signed “CLEANED” label on the equipment.
- 5.2.13 Record the cleaning completion time in the equipment usage log sheet as per SOP.

5.2.14 Frequency

- 5.2.14.1 Type ‘A’ cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week then follow the procedure of type – B cleaning.
- 5.2.14.2 Type ‘B’ cleaning is applicable in case of changeover of product with different actives / colour / 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.

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.

5.3 SETTING OF MACHINE

- 5.3.1 Set the temperatures as per the instruction given in the respective BMR, wait till the tray dryer



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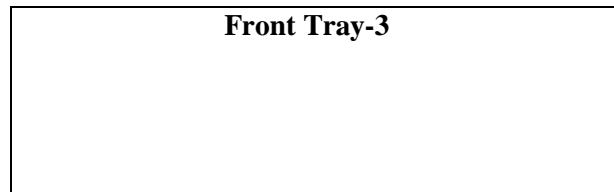
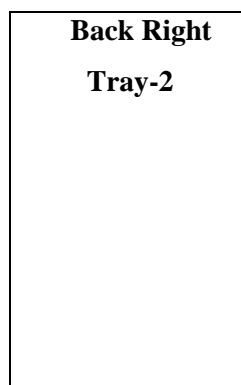
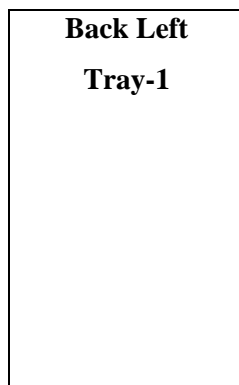
STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

attains required temperature.

5.3.2 Take the tray from VTD, Put the tray on SS pallet and pour the material in to tray with help of SS jug as per respective BMR instruction or about 1-3 liter (Approximately 1-3 kg) material in each tray and spread the material uniformly for quick drying.

5.3.3 After material loading insert the filled tray in to VTD starting to stack them From bottom to top and left to right sequence in following manner.



5.3.4 The numbering is allotted from Left back is no 1; right back is no.2 and front is no.3. This sequences for numbering and loading is following for rest of trays.

5.4 EQUIPMENT OPERATION:

5.4.1 VTD MILLANIUM:

5.4.1.1 Ensure "CLEANED" label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "UNDER PROCESS" label duly filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP.

5.4.1.2 Arrange the trays with the material as describe in the Setting of Machine.

5.4.1.3 Lock the door of Vacuum Tray Dryer.

5.4.1.4 Open all the valve lines.

5.4.1.5 Close vacuum release valve.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4.1.6 Ensure that water line is open that supplies water to vacuum pump.

5.4.1.7 Start vacuum pump by pressing 'GREEN' push button.

5.4.1.8 Racking done if required by following procedure.

5.4.1.9 Close the isolating valve between condenser and receiver.

5.4.1.10 Stop the flow of heating media in dryer.

5.4.1.11 Switch 'OFF' the vacuum pump by pressing 'RED' push button.

5.4.1.12 Open the vacuum release valve.

5.4.1.13 Open the door and remove the tray.

5.4.1.14 Put the tray on SS pallet and rack the material gently with help of SS scoop / SS spatula one by one and keep the tray in to VTD on its respective allotted place.

5.4.1.15 Repeat steps 5.4.1.2 to 5.4.1.13 to restart the process.

5.4.1.16 Sampling done if required by following procedure.

5.4.2 VTD S2 ENGINEERING:

5.4.2.1 Ensure "CLEANED" label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "UNDER PROCESS" label duly filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP.

5.4.2.2 Arrange the trays with the material as describe in the Setting of Machine.

5.4.2.3 Lock the door of Vacuum Tray Dryer.

5.4.2.4 Open all the valve lines.

5.4.2.5 Close vacuum release valve.

5.4.2.6 To start the machine switch ON the knob presented on the PLC panel.

5.4.2.7 Vacuum to be starts by PRESS on the knob.

5.4.2.8 For inlet setting at PLC Press the Star "☉" button

5.4.2.9 Set the required temperature as per BMR Press the Button ▲ to increase and ▼ to decrease the set temperature.

5.4.2.10 The vacuum display on the lower side of the PLC.

5.4.2.11 Racking done if required by following procedure.

5.4.2.12 Close the isolating valve between condenser and receiver.

5.4.2.13 Stop the flow of heating media in dryer.

5.4.2.14 Open the vacuum release valve.

5.4.2.15 Open the VDT door.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.2.16 Take the sample as per respective individual sampling protocol / respective BMR instruction / SOP (in process sampling).
- 5.4.2.17 Repeat steps 5.4.2.2 to 5.4.2.15 to restart the process.
- 5.4.2.18 After the operation is over, close the isolating valve between condenser and receiver.
- 5.4.2.19 Stop the flow of heating media in dryer.
- 5.4.2.20 Switch 'OFF' the vacuum pump by pressing 'RED' push button.
- 5.4.2.21 Open the vacuum release valve.
- 5.4.2.22 Open the door of VTD.
- 5.4.2.23 Unload the material after process completed in to respective IPCs/Bin with the help of SS scoop / SS spatula.
- 5.4.2.24 Remove and destroy "UNDER PROCESS" label.
- 5.4.2.25 Affix "TO BE CLEANED" labels duly filled and signed on the equipment.
- 5.4.2.26 Record all the observations in equipment usage log sheet as per SOP.

6.0 ABBREVIATION (S):

- IPA : Iso Propyl Alcohol
SOP : Standard Operating Procedure
v/v : Volume/Volume
BMR : Batch Manufacturing Record
IPC's : In process containers

7.0 REFERENCE (S):

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

SOP: In process sampling

8.0 ANNEXURE (S):

Annexure - I : Equipment cleaning checklist.

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

Controlled copy (s) : Production department, Quality Assurance



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Reference copy (s) : Production department (Two copy)

ANNEXURE –I

Name of the Equipment	VACUUM TRAY DRYER		
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Clean the trays with 40 to 45 liters of purified water by using nylon scrubber.	
2.	Wash the trays with 35 to 40 liters of purified water.	
3.	Rinse the trays with 15 to 20 liters of purified water	
4.	Clean the internal parts like convection plate and inner SS walls by using CIP pump and Finally rinse the Vacuum Tray Dryer with the 50-60 liters of purified water and remove the water droplets through compressed air.	
5.	Run the vacuum tray dryer for 10 minutes to remove internal moisture.	
6.	Clean outer parts such as body, vacuum releasing chamber, hot water supply and return pipe and door of the equipment with a lint free cloth dipped in purified water.	
7.	Clean the electric panel with dry lint free cloth.	
8.	Wipe the all parts with 70 % v/v IPA solution.	
9.	In case equipment remains idle for 72 hours, re-clean the equipment by wiping with 70 % v/v IPA solution before use.	
10.	Affix duly filled and signed "CLEANED" label on the equipment.	

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.



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STANDARD OPERATING PROCEDURE

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