



PHARMA DEVILS

SOP for Cleaning and Operation procedure of Open fronted containment facility

PROTOCOL No.:

1.0 OBJECTIVE:

To lay down the procedure for cleaning and operation procedure of OFCF.

2.0 SCOPE:

This SOP is applicable for Cleaning and operation of OFCF.

| | |
|---------------|-------------------------|
| Equipment no. | |
| Make | |
| Size | 1990W x 2020 D x 2475 H |
| Location | Dispensing Area |

3.0 RESPONSIBILITY:

Store Executive is responsible for implementing the SOP.

4.0 PROCEDURE

4.1 Cleaning Procedure for batch to batch

- 4.1.1 Switch off OFCF & balances.
- 4.1.2 Dispensing booth & all accessories shall be cleaned with the help of dry fiber free duster.
- 4.1.3 Exhaust ducts & grills shall be cleaned thoroughly.
- 4.1.4 Visual panels, pallets, balance platform & dispensing aids shall be mopped with wet duster if visually looking any stains.

4.2 Cleaning Procedure for product changeover

- 4.2.1 Check OFCF is switched OFF.
- 4.2.2 Clean Area with vacuum cleaner.
- 4.2.3 Pre-caution: Do not point vacuum cleaner nozzle towards the HEPA filters.
- 4.2.4 Wipe from top to bottom S. S. grills or metal surfaces, balances, Ceiling, visual panels, doors etc with a fiber free wet duster.
- 4.2.5 Wipe with a clean, dry cloth and inspect for any stains or unclean areas and repeat the process if not cleaned fully.
- 4.2.6 All stains shall be cleaned with use of 0.2 % Teepol solution and finally clean with wet cloth.
- 4.2.7 Apply 70% IPA solution moping with lint free cloth.
- 4.2.8 Affix the 'CLEANED' labels duly filled and signed as per format attached.
- 4.2.9 Record all observations in "Dispensing Log and Dispensing Area Cleaning Record as given in the format no.

4.3 Operation of OFCF

- 4.3.1 Dispensing area shall be made free of any material of the previous batch/product.



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- 4.3.2 Check the status of the machine and ensure that a 'CLEANED' label duly filled and signed is displayed.
- 4.3.3 Switch ON the electricity supply.
- 4.3.4 Switch ON the panel button by pressing "LIGHT" on the panel.
- 4.3.5 Switch ON the blower motors by pressing "AIR FLOW" button on the panel.
- 4.3.6 Wait till the differential pressure shows constant pressure drop.
- 4.3.7 Observe the differential pressure gauge to show pressure drop between 10 to 16 mm of water, which is safe zone for carrying out dispensing process.
- 4.3.8 In case differential pressure going below 10 mm of water, no dispensing work shall be carried out, as scavenging pre-filters require cleaning. In case the problem persists after cleaning, inform Engineering Dept. executive to rectify the fault.
- 4.3.9 In case differential pressure going beyond 16 mm of water, no dispensing work shall be carried out, as there is possibility that HEPA filters is clogged. Inform engineering department executive to rectify the fault.
- 4.3.10 Record differential pressure at the starting of work and every 4 hours till the end of work in Differential Pressure Record as per format no.
- 4.3.11 Wait for 15-20 minutes for system to get stabilized before commencing dispensing process.
- 4.3.12 Switch ON the balance and check for zero error display or act according to SOP.
- 4.3.13 Carry out dispensing as per SOP no.....

5.0 SAFETY AND PRECAUTIONS:

- 5.1 Observe all safety warnings as displayed in the area.
- 5.2 While cleaning, do not damage the HEPA filter (Ensure that nozzles of vacuum cleaner are never pointed towards the HEPA filter.)
- 5.3 Do not store anything on top of the unit.
- 5.4 Always check pressure reading on magnehelic before starting dispensing.

6.0 REVISION HISTORY:

| Revision No. | Reason for revision | Superseded from and date |
|--------------|---------------------|--------------------------|
| 00 | New SOP | |

7.0 REFERENCES:

Not applicable



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8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

HEPA : High efficiency particulate air

IPA : Isopropyl Alcohol

QA : Quality Assurance

QC : Quality Control

OFCF : Open fronted containment facility

9.0 ANNEXURES

Annexure-I : Open fronted Containment Facility (Dispensing Booth)

Annexure-II : "Cleaned"

Annexure-III : "To Be Cleaned"



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ANNEXURE -II

Cleaned & To Be Cleaned Label

| | |
|------------------|-------------|
| “Cleaned” | |
| | |
| Sign. | Date |
| | |

| | |
|------------------------|-------------|
| “To Be Cleaned” | |
| | |
| Sign. | Date |
| | |