



# PHARMA DEVILS

WAREHOUSE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Warehouse	<b>SOP No.:</b>
<b>Title:</b> Cleaning of Sterile and Non-Sterile Materials Sampling / Dispensing & Others Store Area	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning of Sterile & Non Sterile Materials Sampling / Dispensing & Others Store Area.

### 2.0 SCOPE:

This SOP is applicable for Cleaning of Sterile & Non Sterile Raw Materials Sampling/Dispensing & others Store Area at Raw Material Store in Injection Block.

### 3.0 RESPONSIBILITY:

Operating Person –Warehouse

### 4.0 ACCOUNTABILITY:

Head-Warehouse

### 5.0 ABBREVIATIONS:

%	Percentage
IPA	Isopropyl Alcohol
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedure
WH	Warehouse

### 6.0 PROCEDURE:

#### 6.1 Daily Cleaning of Sampling and Dispensing Area:

- 6.1.1 Store person shall switch ‘‘OFF’’ all electric supplies before cleaning.
- 6.1.2 During Shift of starting cleaning of surrounding area & Walls up to six foot, Change room, Window shall be done by using disinfectant solution as per schedule with lint free cloth or vacuum cleaner.
- 6.1.3 Clean the Waste bin, Pass Box, RLAF, Balance with platform, Dress Cabinet, Cross over Bench, Mirror, Plate stand, Trolley with 70% IPA solution.
- 6.1.4 Inner surface and Hood, Outer surface of RLAF will be cleaned with lint free Cloth followed by its mopping with 70% IPA solution.



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**6.1.5** Officer / Executive warehouse shall intimate to Engineering department for cleaning of lighting fixtures as per cleaning frequency.

**6.1.6** After cleaning of all area, switch 'ON' the RLAF for 10 minutes running to stabilize the Area.

**6.1.7** Cleaning & Sanitation Details of Sampling & Dispensing surrounding area will be recorded in "Cleaning & Sanitation Record" as per Annexure-I.

**6.1.8** **Frequency of area ceiling and Lighting Fixtures.**- Weekly or whenever required

### **6.2** Cleaning of "Sampling/Dispensing Area During Batch to Batch Change Over" (Type – Dry Cleaning):

**6.2.1** After completion of Sampling or dispensing activity, Air Blower will be continuing "ON".

**6.2.2** Clean the Area using under RLAF will be cleaned with Vacuum Cleaner or Lint Free Cloth.

**6.2.3** Used dispensing tools shall be kept in a container labeled with "To be Cleaned" and transferred to the equipment washing area for cleaning as per SOP, "Handling, Cleaning and Drying of Sampling and Dispensing Tools in Injectable Block".

**6.2.4** Hood and Outer surface of RLAF will be cleaned with lint free Cloth.

**6.2.5** In case of two or more API available in BOM, than below mention procedure shall be follow up.

**6.2.6** After Dispensing of an API material, Inner surface and Outer surface of RLAF will be cleaned with lint free Cloth (Dry Cleaning).

**6.2.7** After dry cleaning of RLAF, mopping will be performing with 70% IPA (Wet Cleaning) then starts dispensing of next API as per BOM.

**6.2.8** Before starting and after completion of Sampling/ Dispensing activity container outer surface shall be clean with 70% IPA.

**6.2.9** **Frequency:** Initially / During Batch to Batch Change Over.

### **6.3** Cleaning of "Sampling / Dispensing Area During Product To Product Change Over (Type – Wet Cleaning):

**6.3.1** After completion of Sampling or Dispensing, Air Blower will be switched "OFF".

**6.3.2** Sampling / Dispensing Area under RLAF will be cleaned with Vacuum Cleaner or Lint Free Cloth and the same area will be sanitized with 70% IPA solution.

**6.3.3** Used dispensing tools shall be kept in a container labeled with "To be Cleaned" and transferred to the equipment washing area for cleaning as per SOP, Titled "Handling, Cleaning and Drying of Sampling and Dispensing Tools in Injectable Block".



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6.3.4 Hood and Outer surface of RLAF will be cleaned with lint free Cloth followed by it's mopping with 70% IPA solution.

6.3.5 Air Blower should be Switch 'ON' and allow to run continues for 10 minutes to remove any leftover Residues after Cleaning of the Area.

**6.4 Cleaning for Riser Grill & Pre Filter of RLAF Unit (For Type – Wet Cleaning):**

6.4.1 Air Blower of RLAF will be switched 'OFF' before cleaning of the Filter.

6.4.2 Remove the Pre-filter of RLAF and grill filter surrounding area and replace uncleaned pre-filter and grill with cleaned one, and put uncleaned pre-filter and grill in poly bag labeled with "To be Cleaned" and take to the defined area at utility service floor for cleaning

6.4.3 Concern person shall intimate to Engineering for surrounding area filter cleaning / replacement as per given **Annexure VIII** Titled as "Intimation Slip for Filter Cleaning/ Replacement SOP, Titled "Filter Cleaning of HVAC system.

6.4.4 For RLAF filter cleaning/replacement concern person shall intimate to engineering as per **Annexure IV Title** Intimation for RLAF/LAF filter cleaning/Replacement **SOP titled "Operation and Cleaning of Reverse Laminar Air Flow Unit.**

**6.5 Frequency of Pre & Grill Filter Cleaning:**

6.5.1 Every Product Changeover

6.5.2 After five batches (in case of continue batches of same product).

6.5.3 Dynamic Pass Box grill filter cleaning **Monthly ± 7 days.**

6.5.4 RLAF Filter weekly (in case no production Plan).

6.5.5 Surrounding area grill filter weekly (in case no production Plan).

6.5.6 Change room riser filter cleaning frequency : **Monthly**

**6.6 Cleaning of RLAF & Surrounding Area (For Both Type–Dry & Wet Cleaning):**

6.6.1 Surrounding area RLAF of Sampling & Dispensing room shall be cleaned by using lint free cloth with 70% IPA.

6.6.2 **Note:** During Shift of starting cleaning of surrounding area & Change room shall be done by using disinfectant solution scheduled as per **SOP.**

6.6.3 Cleaning & Sanitation Details of Sampling & Dispensing surrounding area will be recorded in "Cleaning & Sanitation Record" as per **Annexure-I.**



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**6.6.4** During activity of Dispensing Cleaning details related RLAF will be recorded in **SOP**, as per **Annexure-II**.

**6.7 Cleaning of Balance (for Both Type –Dry & Wet Cleaning):**

- 6.7.1** “Switch off” of the balance and disconnect the main switch before cleaning activity.
- 6.7.2** Remove the weight pan from support (if available).
- 6.7.3** Wipe the weight pan and surface of balance with Mop or brush.
- 6.7.4** Clean the weighing pan and surface of balance with 70% IPA solution.
- 6.7.5** Take precaution while cleaning do not disturbed spirit level of balance.
- 6.7.6** Place the balance on its position and adjust the spirit level of balance (if applicable).
- 6.7.7** Place the weighing pan in its place with power connection.
- 6.7.8** Maximum & minimum weight shall be verified and noted to balance verification register.

**6.8 Cleaning of Warehouse Surrounding Area:**

**Note:** *Housekeeping personnel shall clean the waste bin and replace with fresh black polythene Bag and housekeeping personnel shall clean below existing facility in warehouse area.*

- 6.8.1** Housekeeping person shall sanitize the floor by mopping with the schedule of Disinfectant solution and store person enter the daily cleaning activity in **Annexure-IV**.
- 6.8.2** Ceiling, Wall, Door shall be cleaned by lint free cloth with the schedule of disinfectant.
- 6.8.3** Ladder shall be used for reach height of ceiling and walls.
- 6.8.4** Ceiling & Wall cleaning shall be performing once in a week for Approved, Under Test, Quarantine area, Rejected & corridor and other area.
- 6.8.5 Note: Engineering Personnel Shall Perform Following Cleaning in Warehouse.**
- 6.8.6** Light fixtures shall be clean by engineering person.
- 6.8.7** Engineering person shall switch “OFF” all electric suppliers before cleaning.
- 6.8.8** Frequency of **light fixtures** : Weekly or whenever required
- 6.8.9** All weekly cleaning activity record in **Annexure-III**.

**Note:** *Follow up the SOP “Title Cleaning of Pallets, Crates, Racks, Trays and Trolleys” for warehouse accessories like Pallets, Racks, Material Trolley.*



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### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning & Sanitation Record	
Annexure-II	Area / Room Cleaning Record	
Annexure-III	Daily Area Cleaning & Sanitation Record	

**ENCLOSURES:** SOP Training Record

### 8.0 DISTRIBUTION:

- Controlled Copy No.01                      Quality Assurance
- Controlled Copy No.02                      Warehouse
- Master Copy                                      Quality Assurance

### 9.0 REFERENCES:

Reference SOP

### 10.0 REVISION HISTORY:

#### CHANGE CONTROL HISTORY

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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## ANNEXURE-I CLEANING & SANITATION RECORD

**Room Name:**

Date	Name of Previous Product @ Activity	Batch No.	Cleaning time		Code of Cleaning	Done By (Sign & Date)	Checked By (Sign & Date)	Remarks
			From	To				

**Remark:** @Activity Means Daily Cleaning, Area Breakdown Cleaning,

**Code for Cleaning:**

**D:** Type D means- Dry Cleaning

**W:** Type W means-Wet Cleaning



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### ANNEXURE-III AREA/ROOM CLEANING RECORD

**Date:**

**Cleaning Agent:**

**Frequency:** Weekly or whenever required

S.No.	ROOM NAME	CLEANING STATUS OK/ NOT OK	DONE BY SIGN/DT.	CHECKED BY SIGN/DT.	REMARK
1.	Non Sterile & Sterile Sampling /Dispensing area Ceiling/ Wall & Light Fixtures				
2.	Non-Sterile Sampling area Ceiling/Wall & Light Fixtures				
3.	Non-Sterile Dispensing area Ceiling/ Wall & Light Fixtures				
4.	Quarantine Area Ceiling/Wall/ Door & Light Fixtures				
5.	Under Test Area Ceiling/Wall/ Door & Light Fixtures				
6.	Approved Area Ceiling/Wall/ Door & Light Fixtures				
7.	Rejected Area Ceiling/Wall/ Door & Light Fixtures				
8.	Primary Packing Sampling/Dispensing Area Ceiling/Wall/ Door & Light Fixtures				
9.	Primary Packing Under Test/ Approved Area Ceiling/Wall/ Door Light Fixtures				



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## ANNEXURE-IV DAILY AREA CLEANING & SANITATION RECORD

**Cleaning Agent:**

**Date:**

**Frequency: Daily**

S.No.	Room Name	Cleaning Status OK/NOT OK Morning Shift	Room Name	Cleaning Status OK/NOT OK Evening Shift
1.	Quarantine Floor Area		Quarantine Floor Area	
2.	Under Test Floor Area		Under Test Floor Area	
3.	Approved Floor Area		Approved Floor Area	
4.	Rejected Floor Area		Rejected Floor Area	
5.	PPM Sampling/Dispensing Floor Area		PPM Sampling /Dispensing Floor Area	
6.	PPM Under Test/ Approved Floor area		PPM Under Test/ Approved Floor area	
7.	Equipment Washing Floor Area		Equipment Washing Floor Area	
8.	Material Air Lock		Material Air Lock	
9.	Lift Area & Corridor		Lift Area & Corridor	
10.	Waste Bin		Waste Bin	
11.	Receiving Bay		Receiving Bay	

Remark: .....

Morning Shift		Evening Shift	
Done By Sign./ Date	Checked By Sign./ Date	Done By Sign./ Date	Checked By Sign./ Date





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