



**Title:** Replacement of HEPA Filter

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
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**1.0 OBJECTIVE:**

To lay down a Procedure for Replacement of HEPA Filter of Air Handling Unit.

**2.0 SCOPE:**

This SOP is applicable for Replacement of HEPA Filter of Air Handling Unit.

**3.0 RESPONSIBILITY:**

Operating Person – Engineering

**4.0 ACCOUNTABILITY:**

Head – Engineering

**5.0 ABBREVIATIONS:**

AHU	Air Handling Unit
FPM	Feet Per Minute
NMT	Not More Than
QA	Quality Assurance
HEPA	High Efficiency Particulate Air
PAO	Poly Alpha Olefin

**6.0 PROCEDURE:**

**6.1 HEPA Filter shall be Replaced Based on the Following:**

- 6.1.1** During periodic Qualification, if the results i.e. HEPA filter integrity test, are found beyond specified limits.
- 6.1.2** If Air velocity found beyond limit during periodic qualification.
- 6.1.3** Physical Appearance/ Damage & Whenever required.
- 6.1.4** HEPA filter of grade “A” Machine/Equipment’s shall be replaced with a frequency of 05 years ± 06 months or if in any case failure of HEPA during qualification/requalification activity failure/ whenever required.

**6.2 Instruction:**

- 6.2.1** Inform to concerned department & QA department before HEPA Filter Change of AHU.
- 6.2.2** Switch “OFF” the power supply of AHU whose HEPA Filter to be change & other related AHU from panel and affix “**UNDER MAINTENANCE**” slip until work completed.



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- 6.2.3 HEPA filter prior to fixing shall be checked visually for any damage during transportation.
- 6.2.4 Ensure that all the machine/equipment shall be wrapped inside the room before carrying out activity.
- 6.2.5 Up and Down positions of HEPA filter shall be checked before fixing.
- 6.2.6 Certificate of the HEPA filter should also be checked.

### 6.3 Replacement Procedure of HEPA filter:

- 6.3.1 HEPA Filter shall be replaced by engineering and utility personnel in the presence of QA.
- 6.3.2 Replacement of HEPA filter shall be carried out through change control.
- 6.3.3 Remove HEPA filters from Terminal by remove the flange bolts and take out the HEPA.
- 6.3.4 Put the used filter in poly bag for destruction.
- 6.3.5 Clean the filter Housing.
- 6.3.6 Finally fix the New HEPA in the respective housing of Plenum as per directions and tighten the bolts. After fixing seal the gap with food grade silicon.
- 6.3.7 Remove the status label of 'Under Maintenance'.
- 6.3.8 Switch ON the AHU and check the fitting of HEPA, there should be no leakage & perform the Air velocity and PAO test of that respective filter.
- 6.3.9 Air velocity should be within the range as per room specific and leakage should not be more than 0.01% of upstream.
- 6.3.10 After change HEPA filter by new one, Re-Qualification of AHU shall be done.
- 6.3.11 Record for HEPA replacement shall be recorded as per **Annexure-I**.
- 6.3.12 HEPA Filter replacement schedule shall be prepared by Engg. Team as per **annexure no. III**, and replacement activity shall be planned accordingly.
- 6.3.13 After completion of work, Engineering and Utility department shall hand over the equipment to the respective department & QA department.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Filter Replacement Record	
Annexure-II	Status Label	
Annexure-III	HEPA Filter Replacement Schedule of Grade A Machine / Equipment's	

**ENCLOSURES:** SOP Training Record



# PHARMA DEVILS

ENGINEERING DEPARTMENT

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## 8.0 DISTRIBUTION:

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

## 9.0 REFERENCES:

ISO14644-1

## 10.0 REVISION HISTORY:

### CHANGE HISTORY LOG

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





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## ANNEXURE – II STATUS LABEL

<b>STATUS LABEL</b>
<b>FILTER ID:</b>
<b>SECTION :</b>
<b>STATUS OF FILTER:</b>
<b>REMARKS:</b>
<b>CHECKED BY :</b> <b>(SIGN &amp; DATE)</b>



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**ANNEXURE – III**  
**HEPA FILTER REPLACEMENT SCHEDULE of GRADE A MACHINE/ EQUIPMENT**

**Block:**

**Frequency:**

**Year:**

S.No.	Name of Equipment	Equipment ID No	Initial Installation / Last Replacement Date of HEPA	Replacement details	
				Scheduled Date	Execution Date

**Remark (If any):**

**Prepared By**  
**Officer / Executive- Engg**  
**Sign & Date**

**Checked By**  
**Quality Assurance**  
**Sign & Date**

**Approved By**  
**Head QA**  
**Sign & Date**