



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Integrity Testing of HEPA Filter	Effective Date:
Supersedes: Nil	Review Date:
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1.0 PURPOSE

To lay down a procedure for integrity checking of HEPA filter.

2.0 SCOPE

2.1 This SOP is applicable for integrity checking of HEPA filter (PAO) test at.

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

- 3.1.1 ISO 14644- 1, ISO 14644- 2 and ISO 14644- 3.
- 3.1.2 HAS (Health Sciences Authority) 2013.
- 3.1.3 EU GMP Annex.
- 3.1.4 WHO technical report series no. 961, 2011 Annex 5.
- 3.1.5 WHO technical report series no. 961, 2011 Annex 6.

3.2 Attachments

- 3.2.1 Nil.

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

- 4.1.1 **Acceptance criteria:** Measurable terms under which a test results will be considered acceptable.
- 4.1.2 **Operational condition:** Agreed condition where the lean room or clean zone is functioning in the specified manner, with equipment operating and with the specified number of personnel present.

4.2 Abbreviations

- 4.2.1 CC : Change Control.
- 4.2.2 QA : Quality Assurance.
- 4.2.3 SOP : Standard Operating Procedure.
- 4.2.4 Sl. No. : Serial No.
- 4.2.5 HEPA : High Efficiency Particulate Air.
- 4.2.6 PAO : Poly-Alpha Olefin.
- 4.2.7 ISO : International Organization for Standardization.



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4.2.8 WHO : World Health Organization.

4.2.9 HVAC : Heating Ventilation and Air Conditioning.

5.0 RESPONSIBILITY:

5.1 Engineering Person:

5.1.1 To follow the SOP for integrity checking of HEPA filter.

5.2 Engineering Head:

5.2.1 To ensure the procedure for integrity checking of HEPA filter is done as per the process defined in the SOP.

5.3 QA Head:

5.3.1 To ensure implementation of the procedure as per SOP.

5.4 Plant Head:

5.4.1 To ensure implementation of the procedure as per SOP.

6.0 Distribution:

I. Quality Assurance

II. Engineering

7.0 PROCEDURE:

7.1 Before performing PAO testing, ensure that air velocity test is done and observations are meeting the acceptance criteria.

7.2 Ensure that HVAC / UDAF / Clean Cabinet are operational.

7.3 Ensure that the aerosol photometer calibrated and traceability certificate is available.

7.4 The aerosol photometer should have a sampling rate of 28 ± 3 L / min. (1 CFM) with the sensitivity of 10^{-3} microgram / liter.

7.5 Add Poly-alpha olefin (PAO) at 20 to 80 micrograms / liter ratio or suitable aerosol material recommended by the supplier to the aerosol generator.

7.6 Keep the aerosol generator near the air grill / riser / fresh air damper of the Air supply unit.

7.7 Provide compressed air or Nitrogen to the aerosol generator at the pressure of about 20 PSI (equivalent to $1.4 \text{ Kg} / \text{cm}^2$) and visually confirm the generation of aerosol.

7.8 Switch ON the Aerosol photometer and set the upstream concentration to 100%.



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7.9 Once the 100% concentration is established at the upstream side, turn the instrument knob to downstream.

The photometer probe should scan the entire filter face and frame at a position of about 10 to 15 cm from the face of the filter and should be traversed slowly (at a scan rate of not exceeding 5 cm²/sec. For square probe and about 15cm² / sec for rectangular probe), using slightly over lapping strikes.

7.10 After completion of testing, the result shall be entered in the respective format i.e. HEPA filter Integrity Test Raw Data Sheet or check the report of external agency and attach the same. In case online report is generated; same shall be attached with the data sheet.

Note: Remove the diffuser / grill in case of terminally mounted filter

7.11 Acceptance Criteria:

The leakage should not be more than 0.01 % of the concentration.

Note:

In case of tests not meeting the acceptance criteria's, following actions shall be taken:

Stop further testing activities.

Immediately inform the client representative.

Re-start the testing activities after corrective actions taken by the client as per client's quality management system and get clearance.

If the leakage from the flange joints is greater than 0.01 %, repair it either by tightening the nuts or by Applying the silicon sealant and repeat the test.

If downstream PAO concentration observed from the filter media is more than the acceptable limit, filter shall be replaced with new one and qualified.



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REQUALIFICATION / REVALIDATION / PERFORMANCE VERIFICATION:

Grade/ Class of Area	Frequency	
	Re-Validation	Scheduled
A / ISO 5	In case of any major change /	Once in every 6 month
B / ISO 6	modification in the HVAC /	Once in every 6 month
C / ISO 7	UDAF or replacement of the	Once in every 6 month OR once in every year OR based on the Client the HEPA filter requirements but not more than one year
D / ISO 8	HEPA filter	Once in every year

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			