PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Engineering	**SOP No.:**
Title: Integrity Testing of HEPA Filter	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Revision History

Rev. No.	Details of changes	Reason for change
00	NIL	NEW SOP

2.0 OBJECTIVE:

The Objective of this SOP is:

2.1 To describe the procedure for integrity testing of High Efficiency Particulate Air (HEPA) filters being used in Clean Room, De-pyrogenating Tunnel, Laminar Air Flow (LAF) unit and supply/exhaust air unit connected to the critical processes (wherever installed).

2.2 Integrity testing should be performed to detect leaks around the sealing gaskets, through the frames or through various points on the filter media.

3.0 SCOPE:

3.1 This SOP is applicable for the integrity testing of High Efficiency Particulate Air (HEPA) filters being used in Clean Room, De-pyrogenating Tunnel, Laminar Air Flow (LAF) unit and supply/exhaust air unit of .....

4.0 RESPONSIBILITY:

4.1 The Maintenance Engineer shall be:

4.1.1 Responsible to arrange and witness the integrity testing of HEPA filters.

4.1.2 Responsible to take corrective and preventive action, if required.

4.2 The production officer shall be:

4.2.1 Responsible to provide the necessary support to carry out integrity testing of HEPA filters.

5.0 ACCOUNTABILITY:

Head –Engineering Service

6.0 PROCEDURE:

6.1 Integrity testing of HEPA filters should be carried out by the external agency, using the Calibrated photometer.

6.2 Di-octyl phthalate (DOP) /poly alpha olefin (PAO) of Emery-3002 oil should be used as challenge to the upstream of HEPA filter.

6.3 The DOP challenge should introduce the aerosol upstream of the filter in a concentration of 80 – 100 micrograms/liter of air.

6.4 Person carrying integrity testing (from External Agency) should be accompanied with Representative from Engineering, Production and Quality Assurance department.

6.5 Before starting the integrity testing of HEPA filters, ensure that:

6.5.1 Departmental activities are stopped.

6.5.2 Respective equipment is in operation.

6.5.3 The integrity testing of HEPA filters for Depyrogenating Tunnel should be carried out as follows.

6.5.3.1 Tunnel should be in operation.

6.5.3.2 It should be heated till sterilization temperature.

6.5.3.3 Allow the Tunnel to go for cooling below 80C.

6.5.3.4 Carry out the integrity testing of HEPA filters as follows.

6.6 Hold the DOP generator as follows

6.6.1 In case of terminal HEPA filter in clean room --Near the return air riser.

6.6.2 Incase of HEPA filter in LAF --At pre-filter.

6.6.3 In case of HEPA filters in Tunnel --At pre-filter.

6.6.4 Incase of supply/exhaust air unit --At the inlet side.

6.7 Switch `On' the photometer and …..

6.7.1 Set the selector switch to `Clear' mode.

6.7.2 Keep the photometer idle for 5-10 minutes warm up time.

6.7.3 Turn the selector switch to 100% position the least sensitive.

6.8 Connect the compressed air to the DOP/PAO generator and apply compressed air at 20 – 40 psi, which delivers the Di-octyl phthalate (DOP) / poly alpha olefin (PAO) of challenged aerosol.

6.9 Ensure that the challenge aerosol is reached to the upstream of HEPA filter as follows:

6.9.1 Loose the HEPA filter mounting.

6.9.2 Hold the sampling probe of Photometer to the down streamside of HEPA filter.

6.9.3 Photometer should give audio-visual alarm and indicate the 100% penetration.

6.9.4 This ensures that the challenge aerosol is reached to the upstream of HEPA filter.

6.9.5 Tight the mounting of HEPA filters and ensures no leakage using photometer.

6.10 Scan the downstream side of filter (filter matrix, periphery and filter frame) with the sampling probe of photometer in overlapping strokes (at a traverse rate of not more than 10 feet/minute) and read the indicated percentage of penetration on photometer.

6.11 Scanning should be conducted on the entire filter face and frame at a position about one inch from the face of HEPA filter (where ever possible) and to the air discharge side, if discharge duct is connected to any system and/or equipment.

6.12 Any indicated leakage greater than or equal to 0.01% of upstream challenge should be considered unacceptable and warrants:

6.12.1 Replacement of HEPA filters.

6.12.2 A subsequent confirmatory re-test should be performed.

6.13 Report of the Integrity testing should be obtained from the test-carrying agency and should be Preserved by engineering department.

6.14 FREQUENCY:

6.14.1 Integrity testing of HEPA filters should be carried on once in a six months in case of class A & B, and yearly for class D. Such integrity testing can be carried out within the period of 15 – 20 days, earlier than the due date or after the due date.

6.14.2 Additional test should be carried out when air quality is found to be unacceptable, or as part of an investigation into a product sterility failure.

7.0 ANNEXURES:

Nil

8.0 References (S)

Nil

9.0 Glossary

SOP : Standard Operating procedure

No : Number

DOP : Di-octyl phthalate

PAO : poly alpha olefin