



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Particulate Matter count Monitoring	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 objective for checking of air particulate matter counts in the clean room or Under Laminar Air Flow unit (LAF).

3.0 SCOPE:

3.1 This SOP is applicable for the checking of air particulate matter count in the clean room or Under Laminar Air Flow unit (LAF).

4.0 RESPONSIBILITY:

4.1 The Maintenance Engineer shall be responsible:

4.1.1 Responsible for procedure for checking of air particulate matter count in the clean Room or under Laminar Air Flow unit (LAF).

5.0 ACCOUNTABILITY:

Head –Engineering Services

6.0 PROCEDURE:

6.1 Particle counting in the clean room or LAF to be carried out by the external party by (supplier) Using the calibrated Particle counter, during the performance qualification of new facility or Equipment.

6.2 Inform the concerned department in-charge, where particle counting to be done.

6.3 Switch on the AHU/LAF and let it run for 10-15 minutes.

6.4 Switch 'On' the particle counter and set the sampling rate as 1.0 cfm (Cubic Feet Per Minute) Approximately 28.0 liters/ minute. Person carrying flow pattern checking activity should wear following apparel.



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- 6.5 Hold the particle sampler to the working height at different positions and take the print out of the particle count.
- 6.6 Limit of the particle count in the control area is as mentioned below.

Grade	Particle size in μ M	No. Of Particles /ft \geq		Reference
		At rest	At operation	
A	0.5	100	100	GMP Annex-1 Manufacture of Sterile Products.
	5.0	00	00	
B	0.5	100	10,000	
	5.0	00	56	
C	0.5	10,000	100,000	
	5.0	56	560	
D	0.5	100,000	Not specified.	
	5.0	560	Not specified.	

- 6.7 Take the particle count at different places as per the sampling plan.
- 6.8 Switch 'Off' the particle counter.
- 6.9 Get report of the particle count by the external party (Supplier).
- 6.10 The Engineering department should preserve such reports.
- 6.11 Particle of all AHU's and LAF to be carried out once in six months or earlier immediately After any major change in AHU/LAF/Facility.

7.0 ANNEXURES:

Nil

8.0 References (S)

Nil

9.0 Glossary

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cfm : Cubic Feet Per Minute

LAF : Laminar Air Flow