



USER REQUIREMENT SPECIFICATION

Name of Item: Laminar Air Flow

Protocol No.:.....

Functional Area: Quality Control

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- 1.0 Purpose:** To describe the specific requirement of Laminar Air flow unit used in testing of microbiological organisms.
- 2.0 Scope:** This specification is applicable to the Laminar Air Flow unit to be installed at quality control laboratory in microbiology section.
- 3.0 System Description:** Laminar Air Flow unit shall be used for microbiological testing of water samples, raw material, finished products and packaging material etc. It shall be used for general testing, as mentioned above, as well as testing of specific organisms. The general requirement for Laminar Air Flow unit for microbiological testing shall be as per following listed features. However additional features shall also be considered before placing the purchase order.
 - 3.1** It should be of vertical design so as to avoid the space constraint. The working space should be sufficient for performing the activity (preferably 4' x 2' working space)
 - 3.2** Material of construction: Working bench SS316 and outer body: SS316/SS304 (preferably SS316). The working bench should be with dull smooth buffing. It should be equipped with shutter arrangement. The shutter should be transparent and made of heat resistant material.
 - 3.3** It should have the filters arrangement to get the required quality of the air. There should be Prefilters, Filters and HEPA filters of highest and good quality grade so as to reduce the particles to the range of up to 99.97%.
 - 3.4** It should be capable of avoiding cross contamination from user to the testing material and cross contamination from the room due to movements of user.
 - 3.5** The working table shall be equipped with the following:
 - 3.5.1** Should have provision for UV and fluorescent light.



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3.5.2 Should have provision for observing the air pressure

3.5.3 Should have provision for attaching the burner.

3.6 The manufacturer/ supplier should provide complete documentation for validation of the equipment.

3.7 The manufacturer/ supplier should provide the following calibration certificates:

3.7.1 For material used for construction.

3.7.2 All the measuring devices attached to the instrument.

3.7.3 Certificates for HEPA filter used.

3.8 After sales service back up to minimize breakdown time, if any.

4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Individual part certificates, if any.
- Operator's manual

5.0 Other Considerations: The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest. The manufacture/ supplier shall provide the technical assistance to the Engineering Section of the organization for routine maintenance of the equipment at the time of installation of the equipment.

Prepared By:
Date:

Approved By:
Date: