

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION	
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- **1.0 Purpose:** To describe the specific requirement of hot air oven used for drying of glassware used in microbiological and routine analytical activities.
- **2.0 Scope:** This specification is applicable to the hot air ovens to be installed at quality control laboratory in analytical and microbiology section.
- 3.0 System Description: Contamination coming from glassware washing and drying during analytical and microbiological activities is one of the major concerns in the routine activities being carried out in the quality control laboratory. The glassware shall be used for testing of different materials during the manufacturing process and therefore, the glassware used shall be clean and dry. Some of the tests e.g. non aqueous titration requires dry glassware; therefore, to achieve the required target, an efficient system is required for drying in the hot air ovens. Moreover, sometimes the glassware shall also be used after dry sterilization. The hot air ovens shall be used for:

Drying of glassware in chemical laboratory

Drying of glassware in microbiological laboratory

Drying of the glassware after autoclaving

Dry heat sterilization.

The general requirement for hot air oven shall be as under:

- **3.1** Capacity about 300 ltrs. to 350 ltrs.
- 3.2 Material of construction: inner chamber non-reactive, heat resistant material (preferably SS316/SS304). Out surface should be made of SS or mild steel sheet with heat resistant powder coated paint. The inner surface should be mirror polished. The walls should be insulated with PUF / Glass Wool to minimize heat loss and maintenance of temperature uniformity. The inner chamber should be having provision for adjusting shelves for

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keeping different sizes of glassware. The shelves should be made of non reactive material (preferably SS).

- 3.3 It should have rugged heating system to avoid frequent breakdowns in the heating system. The heaters should be made of good quality of Nichrome; and the arrangement of the heaters should be such that all the corners and the middle of the ovens should have the temperature uniformity within the specified range. A provision for circulating fan inside the chamber for uniformity of the temperature.
- 3.4 Temperature range 50°C to 250°C. Temperature controls should be through an efficient system. Temperature display through digital electronic display system.
- **3.5** Provision for door closing system, so that there should not be any leakage from the door.
- **3.6** Ventilation ports for exhaust.
- **3.7** The manufacturer/ supplier should provide complete documentation for validation and calibration of the equipment.
- 3.8 The manufacturer/ supplier should provide the following calibration certificates:
 - **3.8.1** All the measuring devices including temperature, display units etc.
- **3.9** After sales service back up should be from approachable distance so as to minimize breakdown time, if any.
- **4.0 Documentation:** Supplier/Manufacturer shall provide the following document.
 - Calibration certificates for all measuring devices with trace-ability.
 - Test and guarantee certificates.
 - Qualification (DQ, IQ, OQ, PQ) documentation



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- 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.During installation of the equipment the manufacturer/ supplier shall explain the general maintenance procedure for the equipment to the Engineering section.

Prepared By: Approved By: Date: Date: