



**USER REQUIREMENT SPECIFICATION**

<b>Name of Item:</b> Vacuum Oven	<b>Protocol No.:</b> .....
<b>Functional Area:</b> Quality Control	<b>Page No.:</b> 1 of 2

- 1.0 Purpose:** To describe the specific requirement of vacuum oven used for drying of material under vacuum.
- 2.0 Scope:** This specification is applicable to the vacuum oven to be installed at quality control laboratory in analytical section.
- 3.0 System Description:** During test of different materials as per the monographs of the pharmacopeias as well as in-house specifications, the test of loss on drying is one of the important tests. The raw material, finished material, packaging material is required to be tested using the vacuum oven. It is also used for identification test of the material, where the crystals obtained during the sample processing shall be dried under vacuum. It shall also be used for drying of the materials where the drying procedure is recommended prior to their usage e.g. standards used during calibration of melting point apparatus.

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

- 3.1** Capacity about 10ltr to 15ltr.
- 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 two shelves for keeping different samples. 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 oven should have the temperature uniformity within the specified range.
- 3.4** Temperature range ambient to 130°C. Temperature controls should be through an efficient system. It should have temperature display through digital electronic display system.
- 3.5** Provision for door closing system with see through glass window or suitable device which is heat and vacuum resistant.



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

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**3.6** It should have provision for attaching the vacuum with measuring device for measurement of vacuum applied. There should be the provision that on releasing the vacuum there is no splashing of the sample.

**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 and vacuum, 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 i.e. temperature, vacuum.
- 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. During installation of the equipment the manufacturer/ supplier shall explain the general maintenance procedure for the equipment to the Engineering section.

**Prepared By:**

**Date:**

**Approved By:**

**Date:**