USER REQUIREMENT SPECIFICATION	
Name of Item: Autoclave	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 3

1.0 **Purpose:** To describe the specific requirement of autoclave used in microbial testing.

2.0 **Scope:** This specification is applicable to the autoclaves to be installed at quality control laboratory.

3.0 **System Description:** Autoclaves shall be used for sterilizing the media used for microbial testing of water samples, raw material, finished samples and packaging samples in pharmaceutical applications and destruction of media after microbial testing. As per different pharmacopeias i.e. Indian Pharmacoepia, British Pharmacoepia, European Pharmacoepia, United States Pharmacoepia, the test for microbial contamination has to be carried out for different drug substances and drug products as mentioned in individual monographs. Two different autoclaves shall be used for preparation and sterilization of media used in testing and destruction of media after usage respectively. To fulfill the requirements the equipment shall consist of specific features. As per the requirement of international regulatory agencies, the equipment used shall have the following minimum listed specifications. Before purchasing the equipment additional features shall also be considered.

The autoclave used for testing in microbial contamination shall have the following listed features.

3.1 It should be fully automatic and with vertical. The autoclave for destruction of media shall be with manual operation.

3.2 Material of construction: Inner chamber made of SS316 and outer chamber with SS316/SS304 (preferably SS316). The door shall be made of SS316. All the nut bolts should be made of SS316. The gasket should be made of Silicon/Neoprene/Rubber for effective pressure holding inside the autoclave chamber.

3.3 It should have sensors placed at suitable places for mapping and recording of temperature inside the chamber to access the degree of sterilization.

3.4 The working temperature should be above the sterilizing temperature. It should have device for display of temperature and pressure.

3.5 For automatic operative autoclave the temperature and pressure should be controlled through electronic controlling device. There should be data recording device during sterilization cycle and the provision for taking printouts of the complete sterilization cycle.

3.6 There should be safety features for operation of the autoclave. It should have safety features like:

3.6.1 Low water level cut-off device.

3.6.2 Safety valves.

3.6.3 Pressure release valves.

3.6.4 Safety provision in case of opening of door under pressure.

3.6.5 Water level indicator.

3.6.6 Manual operation in case of power failure or failure of electronic controlling device.

3.7 The manufacture/supplier should provide the complete documents for validation of the autoclave.

3.8 The manufacturer/ supplier should provide the following certificates:

3.8.1 For material used for construction.

3.8.2 All the measuring devices including temperature, pressure display units etc.

3.8.3 Calibration of sensors.

3.8.4 Any other calibration certificates, if applicable.

3.9 After sales service back up.

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

- P & I diagram, circuit diagrams which ever applicable
- 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 general maintenance support to the Engineering section at the time of installation of the equipment. The general requirements for the installation of the equipment shall be provided by the manufacture/ supplier.

Prepared By:
Date:

Approved By:
Date: