USER REQUIREMENT SPECIFICATION

Name of Item: UV-VIS Spectrophotometer	Protocol No.:.....
Functional Area: Quality Control	Page No.: 1 of 2

1.0 **Purpose:** To describe the specific requirement of UV-VIS Spectrophotometer used in testing of samples in quality control laboratory.

2.0 **Scope:** This specification is applicable to the UV-VIS Spectrophotometer to be installed at quality control laboratory.

3.0 **System Description:** UV-VIS Spectrophotometer shall be used for testing of raw material, finished products and packaging material etc. It shall also be used for general testing of the materials for identification test as listed in various pharmacopeias. Moreover it shall be used for analytical method development by taking UV scans and subsequently analyzing various samples to reduce the analysis time and increased productivity. The general requirement for UV-VIS Spectrophotometer shall be as per the following specifications. However, additional features shall also be considered.

3.1 It should be easy to operate with user friendly inbuilt software. The system should be standalone unit.

3.2 It should be of double beam for stability, low drift for reliable results.

3.3 It should have the provision for measuring the scan in UV range as well as visible range. It should consist of high resolution and variable wavelength operating parameters. The wavelength range should be from190 nm to 1100 nm.

3.4 It should have provision for attachment of printer to record the results.

3.5 It should have the provision to attach the additional accessories if required.

3.6 The instrument should have features of GLP compliance.

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

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Functional Area: Quality Control	Page No.: 2 of 2

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

- Test certificates for any test solutions used during validation/PQ of the instrument with trace-ability.
- Test and guarantee certificates of the instrument.
- 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 validation/ calibration support for the next 1-2 years.

Prepared By:
Date:

Approved By:
Date: