USER REQUIREMENT SPECIFICATION

Name of Item: High Pressure Liquid Chromatograph	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 2

1.0 **Purpose:** To describe the specific requirement of HPLC (High Pressure Liquid Chromatograph) used in testing of samples in Quality Control laboratory.

2.0 **Scope:** This specification is applicable to the HPLC to be installed at Quality Control laboratory.

3.0 **System Description:** HPLC shall be used for testing of raw material, finished products during release and finished products kept at stability to ascertain the shelf life of the drug product. It shall also be used for general testing of the materials for identification test as listed in various pharmacopeias. More over it shall be used for development of stability indicating analytical method and analysis of impurities in the release as well as in stability samples of drug products. A few products listed in the pharmacopeias require the analysis to be carried out for the drug substance and drug product using the gradient elution and some products require the usage of refractive index for detection. Based on our requirement the HPLC with following specification shall be considered.

3.1 It should have the option for installation and usage of multiple detectors i.e. Refractive Index detector, UV-VIS detector, Photodiode detector. The requirement is for refractive index detector and UV-VIS detector. The UV-VIS detector shall have the detection range from 190 nm to 600 nm.

3.2 It should have the quaternary gradient elution system and multiple programmable options.

3.3 It should be equipped with column oven for analysis of a wide range of products at constant temperature. The column oven shall have the range from ambient to 85°C.

3.4 It should be equipped with an auto sampler system for analysis of large number of samples. The injection volume shall be variable from 1µl to 100µl. the auto sampler tray should have the provision for temperature control for keeping the sample at lower temperature.

3.5 It should be equipped with degasser system for online degassing of the mobile phase for baseline stability and lesser noise during operation at lower wavelengths.

3.6 It should have the controlling option through software. The software should be 21 CFR part 11 compliant. The software should have the facility to customize the report format as per user requirement.

3.7 The manufacturer/ supplier should provide complete documentation for validation and calibration of the equipment at the time of installation.

3.8 The manufacturer/ supplier should have established service back up for maintenance of the equipment with minimum break down time.

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.
- Software validation documents.
- Qualification (DQ, IQ, OQ, PQ) documentation
- 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 manufacturer/ supplier should provide the after sales service for maintenance of the equipment.

Prepared By:
Date:

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Date: