



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: UV Visible Spectrophotometer

Protocol No.:.....

Functional Area: Quality Control

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Name of Equipment: UV –Visible Spectrophotometer

Document Reference Number:

Effective Date:



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1.0 Approval:

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	Signature	Date
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



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3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for UV-VIS Spectrophotometer. The User Requirement Specification (URS) is provided to aid the user through the important components, variables and options necessary to procure a functional UV-VIS Spectrophotometer that meets the user's requirement in the most cost effective method.

The URS is thus provided to the supplier to provide a price quote for the UV-VIS Spectrophotometer supply, including the design and manufacture of the equipment. The URS will be recognized as the integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor will abide by the information and condition set forth by this document as well as purchasing and delivery terms and condition.

The UV-VIS Spectrophotometer of QC Department is used to carry out the tests like assay, identification and related substance etc. It should have certain environmental and facility requirements as per the product requirements.

The system shall have a high degree of precision and accuracy. Any error should not directly affect the quality of the product. The utilities and space involved needs to be discussed prior to the purchase of the equipment.

The unit and its support equipment shall be feasible to be installed in the current building facility. This document encompasses the normal range of UV-VIS Spectrophotometer operation. Obviously technology improvements and new applications may require deviations from these specifications. These specifications are to be utilized as a guide for the user to answer the majority of questions involved in specifying and using the equipment. Addendum may be used to round out the requirements.



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4.0 OVERVIEW DEFINITION

4.1 The UV – Visible spectrophotometer shall have the following features:

4.1.1. The UV-VIS Spectrophotometer shall have updated key panel for operating the instrument. Various screen shall be as follows.

- I. Set screen parameter.
- II. Operate screen parameter.

4.1.2. The UV-VIS Spectrophotometer shall be provided with power fuse and safety features to avoid failure and personal safety, which shall have feature of wear free drive and self-initialization / self-check. No complicated operations or chains shall be used for drive mechanism. UV-VIS Spectrophotometer shall require negligible maintenance.

4.1.3. The UV-VIS Spectrophotometer shall be provided with data collection system along with software requires to run the UV-VIS spectrophotometer. The UV-VIS Spectrophotometer shall have facility to check / verification of all calibration parameters.

4.1.4. The UV-VIS Spectrophotometer shall have digital display screen to set and check the wavelength.

4.1.5. The UV- visible spectrophotometer shall have facility to scan and record the graph.

4.1.6. The UV-Visible spectrophotometer shall be provided with printer.

4.1.7. The UV-Visible spectrophotometer shall have two lamps one gives the light in the range of UV and second for the Visible range.



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4.2 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

Wavelength range	:	190 to 1000 nm
Wave length accuracy	:	± 0.3 nm
Wavelength repeatability	:	± 0.1 nm
Lamp	:	D ₂ and Tungsten
Photometric system	:	Double beam Optics

4.3 The machine is to be used at the following environmental conditions:

- 4.4.1** Room Temperature : 24 ± 2 °C
4.4.2 Relative Humidity : NMT 55 %

4.4 Base Utilities Available:

- Electrical : Single Phase, 230V ± 10 % 50 HZ
Control system requirements : Automatic

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The instruments operation shall be safe, smooth both from user and environmental standpoint.
The UV -visible spectrophotometer shall provision to attach with a computer for all operation and observation.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system will stop automatically upon loss of electricity; will require operator intervention to re-start.

5.3 SAFETY FEATURE:

The UV-Visible spectrophotometer shall have the warning message if any wrong command given during analysis. Data can be save and retrieve as well.



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5.4 ALARMS AND WARNINGS:

The UV-Visible spectrophotometer shall have the warning message if any wrong command given during analysis.

6.0 SALIENT FEATURE:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

The UV –visible spectrophotometer should consist of electrical on / off switch for operation.

UTILITIES:

The Supplier shall specify utility requirement. The User shall ensure that the utilities are available.

Power supply – 230V, Single Phase Pinter.

6.2 MATERIAL OF CONSTRUCTION:

Lamp : D₂ and Tungesten.

Outer body : MS powder coated, rust free.

Cell : Quartz.

6.3 Instruments & controls: Control Touch Screen

7.0 MAINTENANCE:

Do's and Don'ts to be provided

7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment).

7.2 A comprehensive lubrication list and recommended lubrication schedule

7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)

7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals, DQ, Electrical drawing.

8.0 DELIVERY:

The UV-Visible spectrophotometer, with all options, equipment, and the documentation listed below, shall be delivered site. Delivery should be confirmation of the purchase order.



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9.0 DOCUMENTATION:

9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting “as-built” condition with final delivery.

9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “As-Built” condition.

9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:

9.4 Design qualification

9.5 Installation Qualification

9.6 Operational Qualification

9.7 Maintenance and service manuals

9.8 Instrument listing

9.9 Material of construction