USER REQUIREMENT SPECIFICATION (URS)

FOR

UV SPECTROPHOTOMETER

Department :

URS no.

Supersede :

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Issued to mfg / supplier by purchase department _____

USER REQUIREMENT SPECIFICATION

Name of Item: UV Spectrophotometer	**Protocol No.:**.....
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1. Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2. Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

The purpose of the user requirement for UV Spectrophotometer is:
To define the instruction for selection of UV Spectrophotometer for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

4.1 This document is applicable for UV Spectrophotometer intended to use at manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5. Specifications:

5.1 Description of Equipment / System:

The UV Spectrophotometer shall have following components.

- Detectors
- Quartz
- Wave length
- Software with standby mode.

The detail description of the components is as follows;

5.1.1 Detectors:

- The instrument has a facility with 2 Peltier Cooled silicone photodiode detectors (**CDD**) to gives excellent photometric performance.
- Must be software controlled.

5.1.2 Quartz:

- The Quartz Coated Optics ensures longer life of the optics.
- The Quartz can be cleaned if required.

5.1.3 Wavelength:

- Wavelength accuracy of better than 0.3nm and excellent photometric Reproducibility.

5.1.4 Software

- Should have complete control of UV Spectrophotometer.
- Software should have Conforms USFDA 21 CFR PART 11.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
UV Spectrophotometer		Instrument room

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable
- Nitrogen and Carbon Dioxide gas

5.5 Construction:

Not Applicable

5.6 Capacity:

The UV Spectrophotometer must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase.Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Wavelength range, Wavelength accuracy, Wavelength reproducibility, Stray light, Photometric Accuracy, Photometric Reproducibility, Photometric Range, UV resolution, Baseline Flatness, Scanning speeds, Spectral bandwidth parameters must be controlled.

5.9 Acceptable tolerance for control parameters:

Parameter	Criteria
Wavelength range	190 – 1100 nm
Wavelength accuracy	± 0.3 nm
Wavelength reproducibility	Better than ± 0.05 nm
Stray light	200 nm: < 1% T (KCL)
Photometric Accuracy	± 0.003 Abs. At 1Abs.
Photometric Reproducibility	± 0.0003A at A=1
Photometric Range	± 3 Abs
UV resolution (Toluene-Hexane)	> 2.1
Baseline Flatness	0.001 A
Scanning speeds	1-6000 nm/min
Spectral bandwidth	0.5/1/2/4 nm at 500 nm

5.10 Type of control System:

It should have Programmable Pneumatic control system.
Software for complete control on UV Spectrophotometer.
The instrument with large sample compartment to handle wide range of accessories for varied applications.
Special provision for the measurement of turbid samples.
Technology for best signal to noise ratio.
The instrument gives best optical and mechanical stability.
Easily complies the stray light test and resolution test as per all pharmacopoeia.

5.11 Feasible parameters to be set:

Software log in and Shutdown Procedure

5.12 Parameters to be indicated by control systems:

1. Wavelength.
2. Absorption
3. Time and date formatting.
4. Formatting Format for recording data with company's name in header.
5. Analysis details during its run.

5.13 Available utilities:

Utilities required for electric connection can be provided.
Solvents and reagents can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

Software employed for having a control on UV Spectrophotometer, must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

6 Safety:

Electric connection must be connecting with UPS system.
Pressure Gauges, Pressure switches,
Proper equipment earthing shall be provided.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.
- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support
  Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.

- Training
  User training shall consist of equipment training by a qualified trainer.
  Certificates of training shall be provided for each person completing the training program.

- Post Start-up Support
  Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.

- Technical Support
  Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References: