User Requirement Specification (URS)

For

UV/Vis Spectrophotometer

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Date	1403.07.07	1403.07.07	1403.07.08	1403.07.08	1403.07.08

Table of Content

1. Purpose and Scope

This specification is applicable to the UV-Vis Spectrophotometer to be installed at quality control laboratory

2. Responsibility

This document is prepared by the Quality control department of Sina Darou laboratories company.

2.1 Preparation

2.2 Reviewing

2.3 Approval

2.4 Authorization

3. Overview

UV/Vis spectrophotometer shall be used for testing of raw material, finished products and packaging material etc.It shall be used for for general testing of the materials for identification test as listed in pharmacopoeias.Moreover it shall be used for analytical method development by taking UV scans and subsequently analyzing various samples to reduce analysis time and increase productivity .The general requirements for UV/Vis spectrophotometer shall be as per the following specifications.However additional features shall be considered.

4. Operational Requirements

4.1 Function specification

Equipped with internal holmium oxide filter

Optical design: Double beam spectrophotometer with variable spectral bandwidth

Wavelength range:185-1200nm

Spectral bandwidth: variable (0.2,0.5,1.2,4 nm)

Wavelength accuracy (deuterium line at 656.1 nm): +/- 0.1 nm

Wavelength accuracy (at 360.9 nm with holmium oxide filter): +/-0.5 nm

Wavelength reproducibility (at 360.9 nm with holmium oxide filter, RMS) ≤0.02 nm

Zero point of transmission: +/-0.05%T (190-1150 nm; slit 2 nm)

Photometric accuracy Vis: +/- 0.003 A

Photometric accuracy UV: +/-0.010 A

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Photometric reproducibility: ≤0.0005 A

Baseline noise at 500 nm (RMS): ≤0.0001 A

Baseline deviation: +/-0.0005 A (190-1150 nm; slit 2 nm)

Registration speed: Up to 12000nm/min

Min. integration time:0.001 s

Min. data interval:0.02 nm

4.2 Capacity

N.A

4.3 Process Requirements

N.A

4.4 Process Control

N.A

4.5 User Interface

UV software to control the spectrophotometer with a PC

Complies with FDA 21 CFR part 11 regulations

4.6 Data and Security

Audit trails to log all actions on the instrument

Secure electronic records that are synced to a secured database on a PC/multilevel access control

5. Environment

15-35 °C

relative humidity max. 90 % at 30 °C

6. Constraints

6.1 Milestones and Timelines

N.A.

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6.2 Equipment Constraints

N.A.

6.3 Compatibility and Support

N.A.

6.4 Availability/Maintenance

N.A.

6.5 Access Level

N.A.

6.6 Procedural Constraints

N.A.

7. Lifecycle

7.1 Development

.N.A

7.2 Testing

Tested and designated to be compliant with a legal requirements for laboratory instrumentation and developed and produced in compliance with iso9001

7.3 Delivery/ Documentation

The manufacturer must comply with good documentation practice and deliver the necessary

documentation to prove that the facility, system and equipment is constructed according to ICH guidelines and in line with our URS. Thus, it must be documented that the materials used are compliant with PICS guidelines and the appropriate validation tests have been performed. Checklists should be used to validate that all parts of construction, equipment and systems are in concordance with GMP guidelines. These should include, but not be limited to: the material used, quality specification, certificates, test methods/protocols, responsible test person, number of tests performed, test results, transfer plans and reports, IQ, OQ, PQ, Certificate of Analyses (CoA)/Compliance (CoC), validation and documentation

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7.4 Support and training

Warranty: at least 1 year guaranty and 10 years warranty.

Training course should be performed by manufacturer on the site.

8. References

FDA21 CFR Part 11 regulations

9. Attachments

N.A

10. Definitions, Acronyms and Abbreviations

N.A

11. Document Distribution

Department	Version
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