

USER REQUIREMENT SPECIFICATION

Raman Spectrometer

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1. INTRODUCTION

Raman spectroscopy is a form of molecular spectroscopy that yields the chemical fingerprint of measured samples. These unique signatures are used to identify and characterize samples with high reliability at the molecular level. Handheld Raman spectroscopy was designed to satisfy the needs of the pharmaceutical industry at multiple touchpoints along the manufacturing chain. Unlike conventional Raman spectrometers, there is no need to transfer samples to off-site facilities for testing. A handheld Raman spectrometer allows for fully portable testing with an ergonomic design and a simple point-and-shoot format. This provides rapid responses for pass/fail testing or unknown characterization against integrated digital libraries and pre-existing method data.

2. SCOPE

This document describes the characteristics of the Raman spectrometer as part of the Sina Darou's laboratory equipment. The overall objective for this document is to design and demonstrate a system matching the needs of the company.

The overall objective of Raman Spectrometer is to identify raw materials delivered in warehouse.

3. REQUIREMENTS

The instrument should be capable of analyzing all kinds of solid and liquid samples which are Raman active. It should be equipped with measuring tip for vials and measuring tip for bags.

3.1. specification

- Weight: max 1.0 Kg
- Spectral range: 400 cm⁻¹ to 2300 cm⁻¹
- Laser excitation :785 nm
- Laser power : 100 mw
- Detection technique: Orbital Scan to average over the sample
- Spectral resolution:(8-10) cm⁻¹
- Display : Transmissive color TFT with LED backlighting
- Included Standard Library (pharmaceutical) and adaptable to create user library
- Sampling attachments:LWD ,SWD , Contact Ball Probe, Vial Holder

4. Environmental conditions

- indoor usage only, namely in laboratory and warehouse environment
- Nominal function range –20 to +50 °C
- Atmospheric humidity (non condensing): 0 to 95% (relative humidity)

5. Battery and battery charger

- Battery: Rechargeable Lithium ion
- Up to approx. 8 hour usage time
- AC adapter : Optional output 5 VDC/1 A USB for charging
- Input voltage range:100-240 VAC ± 10%, 50/60 Hz

6. Connectivity

Via WIFI or USB

7. Barcode reader

- equipped with Barcode reader (linear barcode and 2d matrix code)

8. Software

complies with FDA 21 CFR Part 11 regulations/ Audit trails to log all actions on the instruments/Reports containing all required information (instrument info, parameters, electronic signatures)/ Secure electronic records that are synced to a secure database on a PC/Multilevel access control, including three predefined access levels and optional password aging and complexity requirements

9. Documentation Requirements

- PV document
- OQ/PQ protocols should be done by supplier on site
- Fully compliant with FDA 21 CFR Part 11 regulations

10. Warranty:

At least 1 year Guaranty and 10 year warranty

11. Training

Training course should be performed on site.