ACCUMAN PR-500

Protable Raman Spectrometer

Change the world for the better through optical sensing

Configuration

Introduction

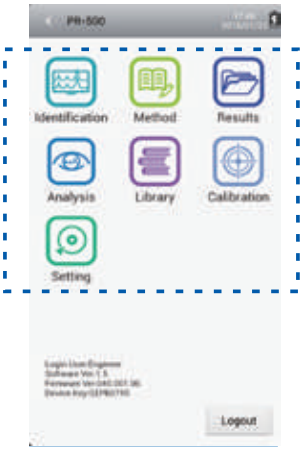
The pharmaceutical industry constantly needs to meet ever-growing compliance and quality standards. Achieving this often brings substantial costs. Many processes require identification of Active Pharmaceutical Ingredients (API) and excipients, often involving sophisticated sample preparation, lengthy testing time, and substantial labor. Opening up packaging also introduces the risk of contamination and exposure. Both risks and costs could be greatly reduced by using a non-destructive, point-and-shoot, instantaneous identification solution, directly at the production site.

The ACCUMAN PR-500 from Ocean Optics Asia is a portable Raman spectrometer, offering rapid, through-packing, accurate identification of pharmaceutical materials. The Raman spectrometer quickly captures the molecular fingerprint of target materials, enabling packet-by-packet or batch-by-batch verification, while delivering the same accuracy as the conventional procedures. At the core of the ACCUMAN PR-500 is the QE-Series spectrometer, which for its superior performance and quality, was used in NASA's projects. This revolutionary solution brings the answer to the growing compliance requirements in the pharmaceutical manufacturing industry.

Key Advantages

- **Speedy**
  High stability and performance integration system, delivering accurate results in seconds,significantly raising efficiency.
- **Accurate and Reliable**
  The core is the Ocean Optics QE-Series spectrometer. Its industry-leading signal-noise ratio and stability allows accurate capturing of molecular "fingerprint", giving highly reliable identification results.
- **User-friendly**
  An ergonomically-designed hand-held probe weighs just 330g, and comes with a high-resolution, touchscreen interface, allowing intuitive, single-hand operation.
- **Customized library**
  Library can be customized according to users' raw material from different vendors, reducing variations and false from standard libraries.
- **Compliance**
  Designed according to GAMP 5, complies with CFR part 11 and GxPs.

Functions and Usage Procedures

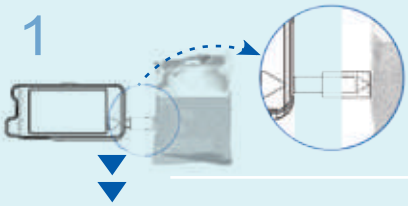


Functions:

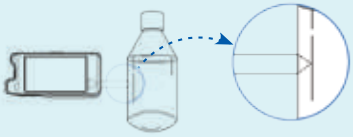
- Identification:Verifies material identity by matching selected method
- Method:Load known material's Raman spectral data into the library, to enable the "identification" function.
- Result:Views all test results
- Analysis:Acquire an unknown sample's Raman spectrum, and find the best match in the library for investigation.
- Library:Add and manage the loaded materials' Raman Spectral data. Allows customization.
- Calibration:Automatic calibrationprocess.
- Settings:Sets basic system options.

Usage Procedures

1



Put on probe cap
For powder in transparent bags or solid samples. Put on probe cap. The probe cap ensures accurate focusing of the laser.



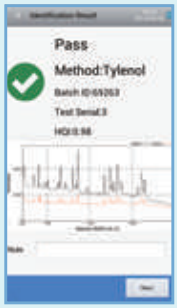
Liquid in transparent vessels:
Do not use probe cap. Rest the probe on the bottle directly.

2 Log in with username and password,PR-500 incorporates a hierarchical user access management, allowing different access for different users. The picture shows the "operator" interface.

3 Open "Identification" function, and select a previously loaded method.

4 Enter batch number. The user can scan a barcode or manually key in the batch number.

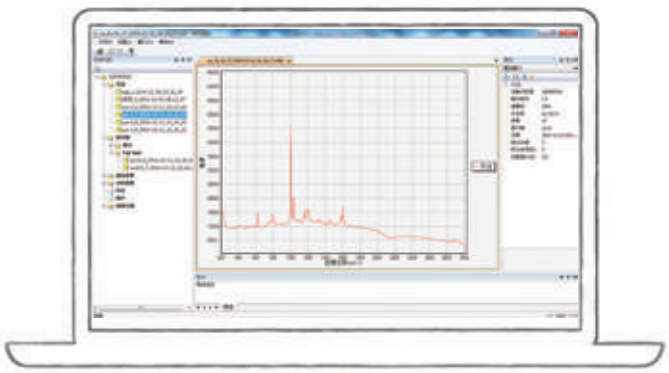
5 Place the target material at the correct position (using probe cap if necessary), and press "acquire", to capture the Raman spectrum.



6 Results (Pass/Fail) are automatically displayed.

PC User Interface

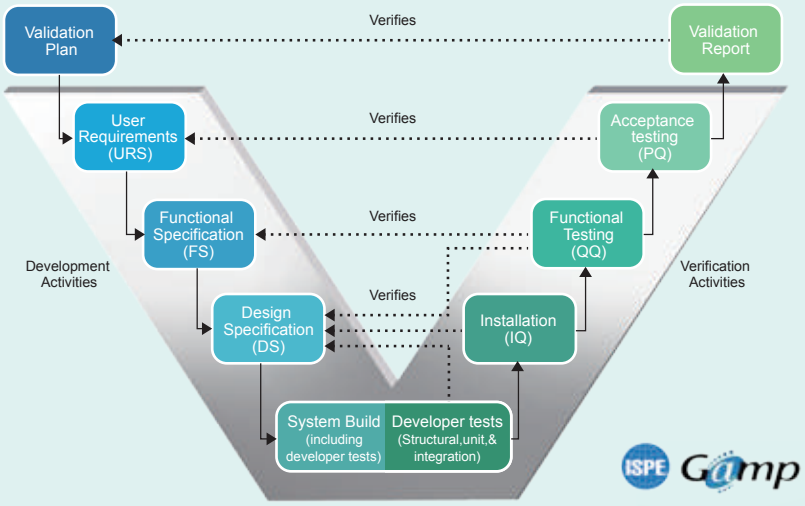
- **Synchronization data**
- **View information**
- **Generate report / print report**
- **Export/import data**
- **Download/backup method and library**



GAMP® 5

Simplified V-model

The GAMP (Good Manufacturing Practice) 5 Guide has been significantly updated to align with the concepts and terminology of recent regulatory and industry developments. These regulatory and industry developments focus attention on patient safety, product quality and data integrity. The biggest change being to provide more clearly defined scalability for effort / deliverables versus the size / complexity of projects, and to align with the various regulatory bodies' emphasis on risk / science-based GxPs.



Related Regulatory Texts

- **PIC/S GMP GUIDE ANNEX 8**

The identity of a complete batch of starting materials can normally only be ensured if individual samples are taken from all the containers and an identity test performed on each sample.

- **(COMPLIANCE PROGRAM GUIDANCE MANUAL PROGRAM)**

At least one specific identity test is conducted on each lot of each component

- **United States Pharmacopoeia**

United State Pharmacopoeia (USP34/NF29) General Chapter <1120> Raman Spectroscopy

- **European Pharmacopoeia**

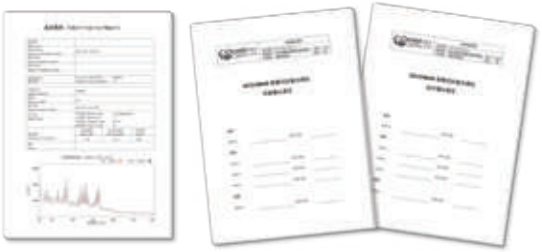
European Pharmacopoeia (PhEur 7.0) 2.2.48 Raman Spectroscopy

- **Pharmacopoeia of the P.R.C**

Pharmacopoeia of the People's Republic of China: 2010 vesion-appendix XIX L Raman Spectroscopy

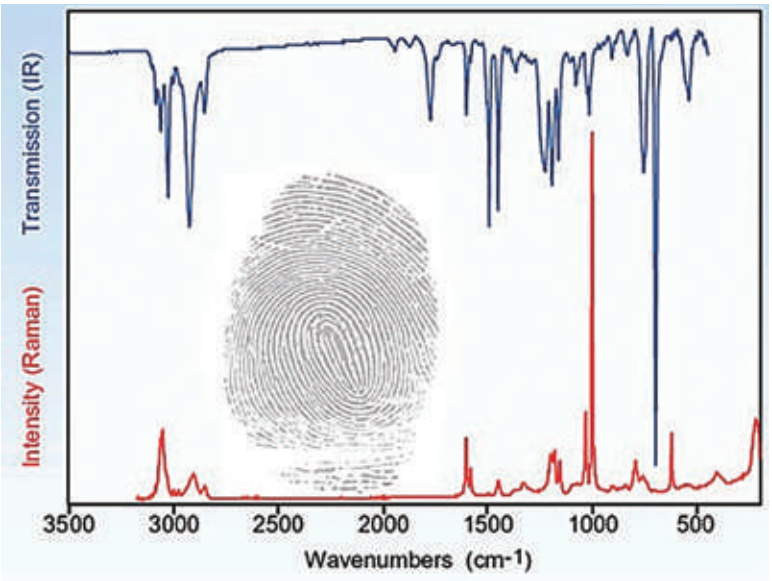
Regulatory Compliance

- Designed according to GAMP 5 guidance, complies with CFR Part 11 and GxPs computerized system requirements
- Hierarchical user access management
- Ensuring data integrity and undeniableness
- Optimized operation procedures. The operator could complete test with few steps.
- Complete 3Q certification service
- Annual calibration and service



Identification report **3Q report**

Raman Applicability



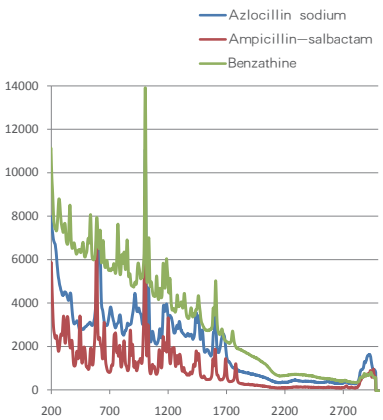
Raman spectrum is a scattering spectrum, discovered by Indian physicist CV Raman in 1928.

Raman spectroscopy has now been widely used for identifying material structure. Similar to infrared (IR) spectrum, Raman spectrum has features specific to molecular structure, hence it is sometimes called “molecular fingerprints”.

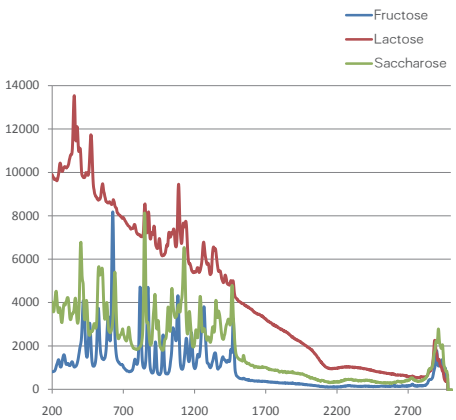
Raman spectroscopy could complement IR spectroscopy, bringing advantages like no need for sample preparation, point-of-use rapid identification, and direct testing of aqueous solutions.

- APIs
- Org. solvents
- Sugars
- Starch
- Inorg. multiprotic salts
  (eg. phosphates)Sulphates, carbonates
- Most oxides, acids and alkalines
  (except for HCl, NaOH, KOH)
- Polymers

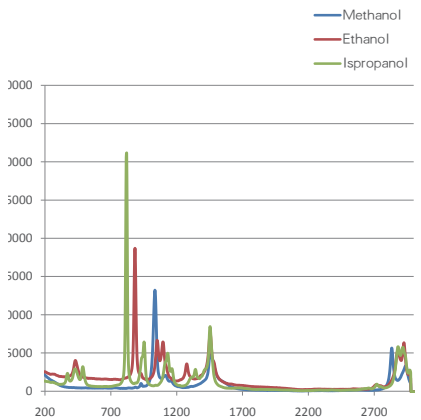
Raw material application



APIs



Excipient



Organic solvent

Specification

Spectral range	200~2000 cm^{-1}	200~3000 cm^{-1}	200~3900 cm^{-1}
Wavenumber resolution	4~6 cm^{-1}	5~9 cm^{-1}	10~12 cm^{-1}
Laser wavelength	785nm±0.5nm		
Laser power	350 mW Max, Adjustable in 10 steps		
Optical parameter	NA 0.22 7.5mm working distance		
Detector	TE cooling Backthinned CCD array		
Signal-Noise-Ratio	10000:1		
Intergration time	0.1~30s		
Screen	4.5'LCD 720p Touch screen		
Bar code	1D , 2D		
Data transfer	USB 2.0		
Data format	.pdf .csv .txt		
Battery	Li-ion Battery , duration time＞5h		
Power adapter	100~240V AC 50/60 Hz		
Weight	(Main unit) 3.8kg , (Probe) 330g		
Dimensions	(Main unit) 29cm×22cm×10cm , (Probe) 15.5cmx7.4cmx2.5cm		
Operating temperature	0~45˚C		
Accessory	Probe cap , calibration cap		
Compliance	USP , EP		
	Designed according to GAMP 5 guidance , complies with CFR Part 11 and GxPs computerized system requirements.		

Optional Accessories

Compact Raman Probe Holder

The holder can be quickly set up to ensure a fixed distance between probe and sample, useful for high throughput, rapid verification

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