

## FT-IR Spectroscopy



## Spectrum Two for Nutraceutical and Traditional Medicine QA/QC

The popularity of nutraceuticals and traditional medicines is soaring as consumers take a keener interest in health and nutrition. As markets for these products develop, tighter regulations are being introduced to ensure industry-wide efficacy, safety and quality. Recent legislation in North America and the EU has applied pharmaceutical manufacturing

standards to these industries, meaning producers must now comply with Good Manufacturing Practice (GMP) regulations. Failure to demonstrate compliance can lead to serious repercussions; the FDA, for example, is sending warning letters and taking non-compliant suppliers to court.

As experts in pharmaceutical compliance, PerkinElmer can help you navigate safely through the regulations that govern nutraceutical and traditional medicine production. Our longstanding experience and knowledge of the highly regulated pharmaceutical industry will help you undertake compliant sample testing, with complete confidence.

### IR: the trusted testing method

Widely used in the pharmaceutical industry, FT-IR is accepted by the FDA and applicable to the analysis of nutraceuticals and traditional medicines. The technique is quicker, cleaner and less expensive than alternative techniques such as HPLC and TLC, and can be practised by anyone without needing an extensive scientific background.

Spectrum Two™ makes sample testing faster and easier than ever before. Non-expert operators can obtain clear, compliant IR results in minutes. Complemented by an industry-specific resource pack, the instrument is designed to deliver rapid, consistent and accurate answers, every time.

### Test Nutraceuticals with Confidence

The Spectrum Two Nutraceutical and Traditional Medicine QA/QC Resource Pack is designed to help users new to IR understand and achieve regulatory compliance. Collating all requirements and best practices, the pack facilitates rapid analysis and release of materials in accordance with FT-IR pharmacopoeia regulations where appropriate. This ensures testing protocols are performed to GMP-compliant specifications and will meet the requirements of internal and external auditing processes.

Testing parameters from the seven pharmacopoeias listed are provided in document form and stored electronically within the Spectrum™ 10 software as part of the pharmacopoeia ID test. This ensures analyses meet strict regulatory requirements and saves time by eliminating the need to source correct testing information.

The pack includes approved sampling methods and best practice for compliant test protocols, as well as a sample preparation SOP that addresses the unique characteristics of nutraceuticals and traditional medicines. 21 CFR technical compliance documents, botanical reference spectra and a selection of application studies are also provided. Plus, for the set-up and implementation of training programs, you can access PerkinElmer's knowledge and experience via the Educational Resource and Introductory Kits.

### Service You Can Count On

PerkinElmer offers a range of support services designed to help you maximize instrument uptime and drive the productivity of your IR testing processes. OneSource® Laboratory Services from PerkinElmer offers a global team of certified, factory-trained customer support engineers in more than 150 countries around the world. Flexible and scalable, OneSource provides a comprehensive suite of services to meet your specific instrument maintenance and repair needs, including validation and compliance, asset management and laboratory relocation, software and hardware upgrades, or education and training.



For more information, visit [www.perkinelmer.com/spectrumtwonutraceuticals](http://www.perkinelmer.com/spectrumtwonutraceuticals)

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