SPECTROSCOPIC SOLUTIONS FOR

Pharmaceutical Quality Control via FT-IR

Validation support for complete peace of mind.

Innovation with Integrity

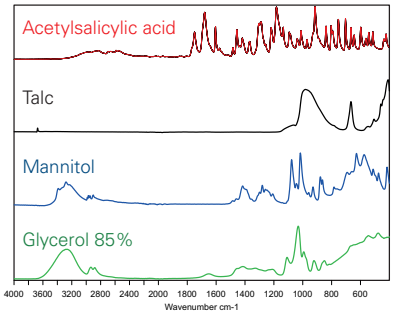
The development and manufacture of pharmaceutical products is subject to the strict rules of good laboratory and manufacturing practice. Bruker offers FT-IR instrumentation and software in full compliance with the GMP/GLP/cGMP regulations.

Fourier Transform Infrared (FT-IR) spectroscopy, also known as molecular spectroscopy, uses infrared light to induce molecular vibrations within the sample being analyzed. These vibrations are visualized in the infrared spectrum as absorption lines. Each chemical substance has its own infrared signature, just like a finger print. Therefore, infrared spectroscopy is able to identify substances and quantify ingredients.

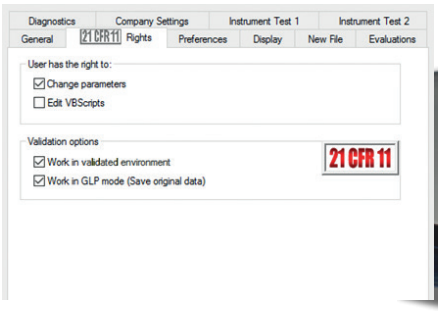
Use it for all sample types:
- APIs, binders, fillers, excipients
- Powders, granules, tablets
- Liquids, creams, pastes
- Coatings, lubricants

Ideal for many applications:
- Identification of particles and contaminations
- Deformulation characterization of unknown samples
- Quantification of components
- Polymorphism analysis

Instrument Features & Compliance
- Validated spectroscopic software, GLP compliant
- Global audit trail for automatic tracking and documentation of all activities
- Comprehensive system validation manuals
- 21 CFR Part 11 compliance
- Smart archiving



The IR-spectrum: Chemical fingerprint of API and excipients.



cGMP/GLP and 21 CFR part 11 compliant, validated OPUS spectroscopic software.

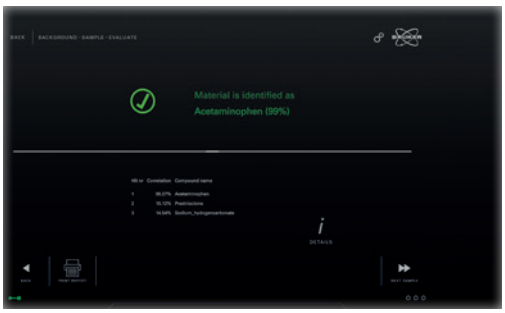
Troubleshooting

Pharmaceutical products have to be free from contaminations like particles in liquid formulations or inclusions in tablets. Such contaminants are often extremely small and therefore hard to analyze. However, to successfully find the source of contamination it is required to determine the chemical nature of the particle or inclusion. FT-IR microscopy allows to measure smallest structures and to determine their chemical composition.

Measurements with a local resolution in the micrometer range allow characterizing the composition of a tablet or lyophilisate. Mapping measurements on the sample reveal the distribution of individual components, e.g. the API, excipients and even different polymorphic forms of the same compound.

Quality Control

Identity control using ATR (attenuated total reflection), typically is performed without sample preparation providing the result within seconds: Place the sample, apply clamp, measure 10 seconds – done!



OPUS Touch offers enhanced productivity through the intuitive touch-based workflows that guide you through measurements.

As analysis result the user is informed if the inspected sample is the correct material. If the sample is completely unknown large reference databases allow an automated determination.

Data Security, Integrity and Traceability

The OPUS spectroscopic software is validated and fully compliant with Good Laboratory Practice (GLP) regulations:

- Extended user and password management
- Access control, automatic system audit trail
- Audit trail for spectra and evaluation methods
- Original data cannot be deleted or overwritten
- All data (spectra, evaluation, results, reports) is stored in a single file to guarantee data integrity and simplify archiving
- All functions in a single software
- Full Title 21 CFR part 11 compliance

OPUS Validation Program

The OPUS Validation Program (OVP) is a software tool for comprehensive instrument qualification.

- Instrument qualification protocols for OQ, PQ, PhEur 2.2.24, PhJP 2.25 and USP <854>
- Fully automated instrument qualification using the Internal Validation Unit (IVU)
- Generation of non-editable test reports
- Continuous monitoring of system validation status
- Quick performance test on program start and when changing measurement accessories

Bruker Optics is continually improving its products and reserves the right to change specifications without notice.
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