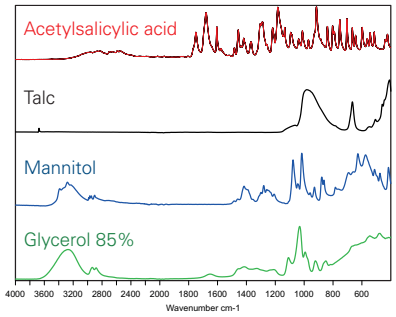
Pharmaceutical Quality Control via FT-IR

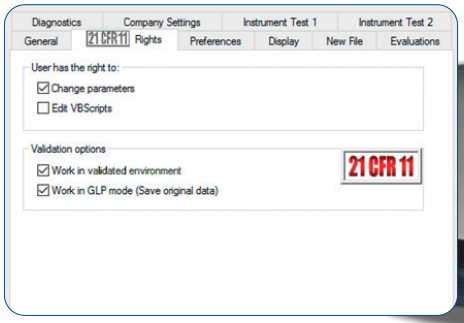
The development and manufacture of pharmaceutical products is subject to the strict rules of good laboratory and manufacturing practice. Bruker offers FT-IR instrumentation and software in full compliance with the GMP/GLP/cGMP regulations.

Fourier-Transform-Infrared (FT-IR) spectroscopy also is called molecular spectroscopy. Infrared light induces molecular vibrations of the molecules in the analyzed sample. 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:
  - APIs and excipients
  - Packaging materials
  - Identification of particles and contaminations
  - Characterization of unknown samples
  - Polymorphism
  - Quantification
  - Powders, granules, tablets
  - Liquids, cremes, paste
  - Binders, coatings, fillers, lubricants
- Pharma Features:
  - Global Audit Trail. Smart Archiving.
    Everything is automatically tracked and documented.
  - Comprehensive system validation manuals
  - Validated spectroscopic software, GLP compliant
  - 21 CFR part 11 compliance



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!

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

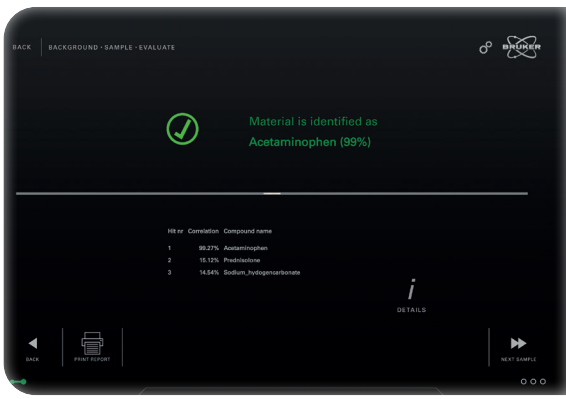
The OPUS spectroscopic software is validated and fully compliant with Good Laboratory Practice (GLP) regulations:

- 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



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

Technologies used are protected by one or more of the following patents:
US 7034944; DE 19940981

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www.bruker.com/optics

Bruker Scientific LLC
Billerica, MA · USA
Phone +1 (978) 439-9899
info.bopt.us@bruker.com

Bruker Optics GmbH & Co. KG
Ettlingen · Germany
Phone +49 (7243) 504-2000
info.bopt.de@bruker.com

Bruker Shanghai Ltd.
Shanghai · China
Tel.: +86 21 51720-890
info.bopt.cn@bruker.com