

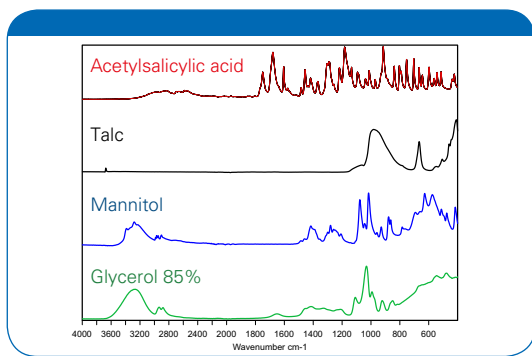


## • **Quality Control and Troubleshooting** Pharma

Bruker's FTIR spectrometer system ALPHA II provides a quick, reliable and universally applicable identity control of your incoming raw materials. With the FTIR microscope LUMOS even complex or unknown samples can be characterized very accurately. This makes the LUMOS a powerful analytical tool in product development and troubleshooting.

Both systems are prepared for comprehensive system validation to fully comply with the regulations in pharmaceutical manufacturing.

- Incoming goods inspection
  - APIs and excipients
  - Packaging materials
- Troubleshooting
  - Identification of particles and contaminations
  - Determination of wrong composition
- Characterization of unknown samples
  - Bulk
  - Polymorphism
  - Tablets
  - Homogeneity of coatings
- Quantification of API and excipients
- Universally applicable
  - APIs
  - Powders, granules, tablets
  - Liquids
  - Binders, coatings, fillers, lubricants



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



Analysis of small samples with the FTIR microscope LUMOS.

## Quality Control

Identity control using the ALPHA II 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. Furthermore differences in the composition of the tested material compared to reference batches are detected. If the sample is completely unknown large reference databases allow an automated determination.

The use of the ALPHA II is very simple: Even untrained personnel can perform the analysis. The software guides the operator through measurement, evaluation and reporting step by step.

## 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. The FTIR microscope LUMOS allows to measure smallest structures and to determine their chemical composition.

Technologies used are protected by one or more of the following patents:  
US 7034944; US 5923422; DE 19940981

LUMOS is a stand-alone system that is very easy to use due to its full automation and intuitive analysis software. Furthermore its design is very compact and space saving. Due to these features the LUMOS is very suitable for the use in routine analysis.

In addition the LUMOS generates precious information in the field of pharmaceutical development and reverse engineering. 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.

Also the different layers of complex composite materials like multilayer films used for packaging can be identified.

## Validation

ALPHA II and LUMOS are prepared to fully support any validation requirements; from the installation qualification (IQ) to operation (OQ) and daily performance qualification (PQ).

## FTIR Spectroscopy

Fourier-Transform-Infrared (FTIR) –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.

### Advantages IR-Method

- Short analysis time (< 1 minute)
- No / minimal sample preparation
- Nondestructive
- Low running costs:
  - Long life time
  - No disposables
  - Low power consumption

### Bruker Optics

Bruker is the leading manufacturer and worldwide supplier of Infrared and Raman spectrometers.

It offers the world's most comprehensive FTIR product line that includes routine to research grade FTIR spectrometers; from very compact to the highest resolution spectrometers for various quality control and research applications.

Customer support is provided worldwide by qualified and experienced application and service personnel.

**Bruker Optics is ISO 9001 and ISO 13485 certified.**

Laser class

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