VALIDATION SOLUTIONS FT-IR SPECTROSCOPY

ALPHA II Validation and Pharma Package

For Compliant Quality Control

Innovation with Integrity

About the Use of FT-IR in Pharmaceutical Manufacturing

Infrared spectroscopy (IR) is a key tool in pharmaceutical production and quality control, used globally in routine inspections and SOPs. Bruker's Pharma Packages simplify this process with a compact, easy-to-use system that ensures reliable, compliant measurements from start to audit - making daily lab work stressfree and more secure.

What the Pharma Analyzer offer

From storing and managing data to streamlining user experience. The ALPHA II together with the software OPUS TOUCH offer easy quality control and tailored role management:

- Predefined analytical workflows
- Complies to all major pharmacopoeias
- Easy operation - no expert skills required
- Software follows the ALCOA+ principle
- LIMS connectivity and active directory
- Complies to FDA title 21 CFR part 11
- Strict data integrity mode

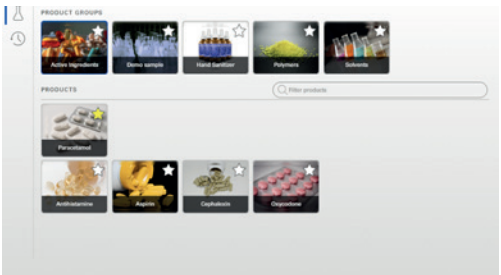
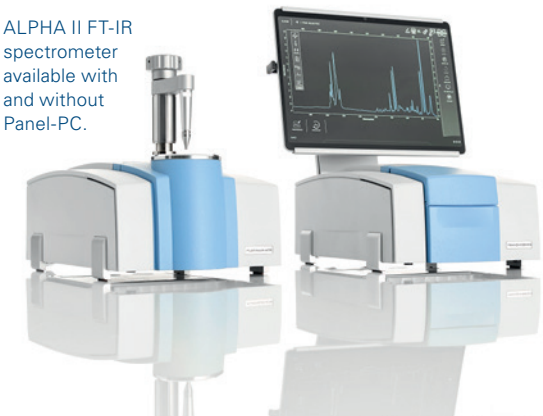


Fig. 1
Easy method selection via according product picture.



ALPHA II FT-IR spectrometer available with and without Panel-PC.

The Complete Package: OPUS TOUCH

OPUS TOUCH enables easy and fast operation of the the ALPHA II, ensuring full data integrity throughout the analysis process.

Fig. 2
OPUS TOUCH features easy user management ❶, spectra signing ❷, audit trail ❸ and much more.

The Validation Package includes:

- ALPHA II FT-IR Spectrometer (Base modul)
- OPUS-TOUCH software for intuitive and convenient IR analysis
- Validation software for 21 CFR Part 11 conformity and data integrity (ALCOA+ principle)
- System Validation Manual for the ALPHA II

Required:
- QuickSnap sampling front module(s) of your choice

Optional:
- MS Surface PC and integrated tablet holder
- Certified reference standard material and software for qualification of the ALPHA II according to PhEur 2.2.24
- ATR Polystyrene standard reference material "BRM 1921" for measurement by ATR technique

Recommended:
- Certified engineer installation available

The Pharma Package includes:

- FT-IR Spectrometer with Platinum Diamond-ATR QuickSnap Sampling Module
- OPUS-TOUCH Software for intuitive and convenient IR analysis
- Validation software for 21 CFR Part 11 conformity and data integrity (ALCOA+ principle)
- System Validation Manual for ALPHA II
- Software package for storing and managing data in a database
- Autonomous Identifier on the OPUS TOUCH software
- Quick Compare method for pharmaceutical substances
- ATR-FTIR Pharmaceuticals Library
- Certified reference standard material and software for qualification of the ALPHA II according to PhEur 2.2.24
- ATR Polystyrene standard reference material "BRM 1921" for measurement by ATR technique
- Approximately 5% price reduction for ALPHA II Pharma Analyzer Package

Optional:
- Accessory for transmission analysis
- MS Surface PC and integrated tablet holder

Recommended:
- Certified engineer installation available

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