Product Note M189-06/20

ALPHA-II/PHA
ALPHA II Pharma Analyzer for Compliant Quality Control

The Pharma Analyzer is a dedicated system for quick and reliable finished product and incoming goods quality control.

About the use of IR in pharmaceutical manufacturing

Infrared spectroscopy (IR) is one of the most basic analytical methods for the production and development of pharmaceuticals. Across the globe, it's part of daily incoming goods inspection and countless SOPs for quality control.

And of course, IR spectroscopy and its instruments are subject to numerous strict regulations and guiding principles. Now, Bruker takes some weight off their customers' shoulders with the Pharma Analyzer.

It is a dedicated and complete solution that provides reliability and security from measurement to final audit. As a compact system with a footprint the size of a laptop, it fits in any lab and easily takes care of your daily quality control business.

For operators, lab managers, admins and auditors

The Pharma Analyzer addresses the needs of the four main FTIR user groups in pharmaceutical manufacturing.

Operators and lab managers will benefit from easy analytical workflows, method setup and highest data integrity, while administrators have complete user manangement, instrument access and data storage control.

Lastly, auditors quickly check and export spectra history and audit trail without the need for additional softwares.

What the Pharma Analyzer offers:

It's an agile plug and play solution for the analysis of pharmaceutical materials. It is based on the affordable and robust ALPHA II FTIR spectrometer. It is not only cost-efficient and user friendly but also 100% reliable:

- Predefined analytical workflows
- Complies to all major pharmacopoeias
- Easy operation - no expert skills required
- Software follows the ALCOA+ principle
- Connectivity to local or online servers
- Complies to FDA title 21 CFR part 11
- Strict data integrity mode

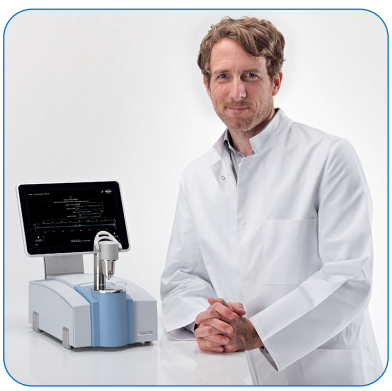

Figure 1: ALPHA II FTIR spectrometer with optional touch-PC (left) and powdered sample being placed on the Platinum ATR accessory (right).

Figure 2: OPUS TOUCH features easy user management (1) , spectra signing (2), audit trail (3) and much more.

About the system validation manual

The system validation manual covers the whole qualification for the complete spectrometer system (hardware and software). It contains Design (DQ), Installation (IQ), Operational (OQ) and Performance Qualification (PQ).

The manual comes with software release documentation, complete test reports, test data and macros and ready to use log forms for extensive validation documentation.

The OPUS validation programm: OVP

The OPUS Validation Program (OVP) is an integrated software tool for comprehensive instrument qualification. It provides:

- Instrument qualification protocols for OQ/PQ according to major intl. pharmacopeias (Ph.Eur. 2.2.24, USP 854, CP, IP, JP 2.25)
- Internal Validation Unit (IVU) for automated OQ/PQ
- Continuous monitoring of system validation status
- Performance tests upon system start or change

The complete package: OPUS and OPUS TOUCH

The Pharma Analyzer is operated by OPUS TOUCH for easy and fast analyses. For creation of valid evaluation methods Bruker's powerful OPUS spectroscopic software is used. Both software interfaces provide full data integrity.

Full validation package. Fully compliant solution.

The Pharma Analyzer and its software are designed from the ground up to be operated under the strict regulations of the pharmaceutical industry, including cGMP/GMP, all major pharmacopoeias and, of course, 21 CFR Part 11. Its software was developed to entirely serve the ALCOA+ principle, meaning your data is stored safely, securely and attributable, whether on local or online servers.

- System complies to 21 CFR p11 and follows ALCOA+
- Includes system validation manual (DQ/IQ/OQ/PQ)
- Internal validation unit for automated OQ/PQ tests
- Validation service by certified engineer (IQ/OQ/PQ)
- Certified standard reference material (integrated in IVU, external for ATR)

The Pharma Analyzer includes

- ALPHA II spectrometer with diamond ATR module
- O/IR8+ OPUS spectroscopic software
- O/TOUCH OPUS-TOUCH software
- O/VAL package for data integrity (ALCOA+ principle)
- S010/SYS System Validation Manual
- S020/D Installation and IQ/OQ/PQ validation services
- S030-M Certification according to PhEur 2.2.24
- BRM1921-ATR Polystyrene standard "BRM 1921"
- 1025052 ATR-FTIR spectral library for pharmaceuticals
- 1841388 ATR-FTIR verification method for drugs and excipients, validated

Recommendation:

- CS86-A+ integrated touch-PC
- OPUS/SEARCH for unlimited search functionality

Validation options:

- S9xxx Various service and maintenance contracts
- S905-OPVAL extension of service contract and update of software and system validation manual

General options:

- C295-W/D WLAN-Adaptation; for wireless operation
- W303/D-U for operation in high-humidity locations
- S202/DII protective trolley for ALPHA II + touch-PC
- Training courses and application trainings
- Additional multipurpose spectral libraries (e.g. polymers)