



• System Validation ALPHA II · INVENIO · LUMOS II

The development and manufacture of pharmaceutical products is subject to the strict rules of good laboratory practice. Bruker offers comprehensive system validation that provides the documentation and procedures needed to use FT-IR spectroscopy in compliance with the GMP/GLP/cGMP regulations.

- Fully automated test routines for OQ, PQ, PhEur 2.2.24, PhJP 2.25 and USP <854> using an integrated certified reference standard
- System installation by certified service engineers
- 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
- Active Directory (AD) Authentication
- Ph.Eur. 5.24 compliance for imaging

Instrument Qualification - Fully Automated

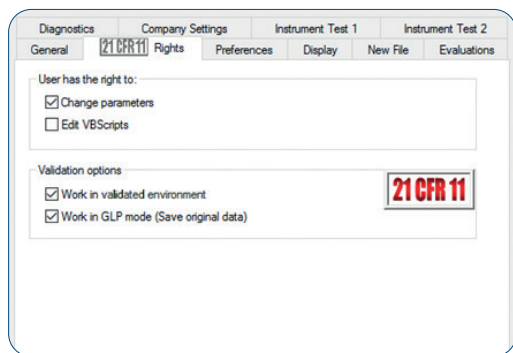
Bruker's FT-IR spectrometers ALPHA II and INVENIO as well as the FT-IR microscope LUMOS II are prepared to fully support your validation needs; from the design qualification (DQ) to daily performance qualification (PQ). Integrated certified reference standards and appropriate software protocols ensure fully automated instrument test routines for Operational (OQ) and Performance Qualification (PQ). Validation periods can be set to your individual needs, and the system status light warns the user when the validation expires.

Validation Services

Bruker's comprehensive system validation manual provides all related documentation and guides you through all necessary validation procedures. Validation, instrument installation and annual certification is offered by Bruker's factory trained, certified service engineers, which further reduce the cost of compliance.

Reference Standards for Instrument Qualification Protocols

The regulated pharmaceutical industry requires scientific instruments to be qualified with certified reference standards. The Internal Validation Unit (IVU) of ALPHA II, INVENIO and LUMOS II incorporates a certified polystyrene standard. Its certification according to PhEur 2.2.24 can be performed on new spectrometers and systems already in use. Using this standard the OPUS/PHEUR2224 software runs fully automated instrument test routines that fully comply with US, European and Japanese Pharmacopeia.



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

OVP - PQ Test Protocol	
Company:	Bruker Optics GmbH
Operator:	Administrator
Instrument Type:	Lumos Transmission LM-MCT Md ZnSe
Optics Configuration:	Transmission w/ MIR, ZnSe, LM-MCT Md [External Pos. 1]
Accessory:	None
Instrument Serial Number:	101
Instrument Firmware Version:	1.352 Dec 04 2012
OPUS/DB Version:	OPUS 7.2 Build: 7, 2, 139, 1294 / DB: 7.2.139.1294
Overall Test Result:	PASSED
Test expires:	11.06.2015, 12:24:33 (GMT+2)
Test Date/Time:	11.06.2014, 12:24:33 (GMT+2)
Test Spectra Path:	C:\OPUS_7.2.139.1294\validation\Data\20140611122433
Date of last PQ Reference Measurement:	10.06.2014
Comment:	
Signal to Noise Test	
Minimum Signal to Noise Limit (area 1):	1000
Signal to Noise measured:	4718
100% Line Test	
Maximum 100% Line Deviation:	2.0
Measured 100% Line Deviation:	0.10
Interferogram Peak Test	
Minimum Amplitude[%]:	70
Measured Amplitude[%]:	102.1
Energy Test	

Automatically generated non-editable instrument qualification protocol

System Validation Manual

The System Validation manual covers the qualifications for the complete spectrometer system (hardware and software):

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

The manual comes with a CD including:

- Software release documentation
- Complete test reports
- Test data and macros
- Ready to use log forms for extensive validation documentation

Data Security, Integrity and Traceability

The OPUS spectroscopic software is validated and fully compliant with Good Laboratory Practice (GLP) regulations. All functionality to produce and secure reliable analytical data is included:

- 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

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

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

21 CFR Part 11

Title 21 CFR Part 11 are regulations issued by the FDA that define standards under which electronic records and signatures can be considered to be equivalent to paper records. OPUS/VALIDATION offers all the features required for full 21 CFR Part 11 compliance, including electronic access control to software and electronic signatures, comprehensive audit trails, and an integrity check for spectra and methods.

Ph.Eur. 5.25

The LUMOS II offers FPA imaging according to the chapter "Chemical Imaging" (5.24) of the European Pharmacopoeia. Thanks to Bruker's patent-pending PermaSure+ technology, our FPA imaging provides the same level of wave-number accuracy as single-element detectors.

Validation Options

- OPUS spectroscopic software, basic features:
 - OPUS Validation Program (OVP) with instrument qualification protocols for OQ and PQ
 - cGMP/GLP compliance
- S010/x System Validation Manuals assisting the validation (DQ/IQ/OQ/PQ) of the basic spectrometer system, extensions (e.g. external accessories), and the OPUS spectroscopic software.
- S020/x Validation services (IQ/OQ/PQ) for the basic spectrometer system and extensions (e.g. external accessories)
- S030/M Option to test an MIR spectrometer according to PhEur 2.2.24 and PhJP 2.25. Includes
 - Certification of standard reference material polystyrene BRM1921
 - O/PHEUR2224 software package with instrument qualification protocols for PhEur 2.2.24 and PhJP 2.25.
- S030/MR Recertification of standard polystyrene reference material BRM1921 according to PhEur 2.2.24 after expiry of the certification period.
- O/VAL, OPUS/VALIDATION package for 21 CFR part 11 compliance of the OPUS spectroscopic software. Contains functionality to apply electronic signatures on spectral data, experiment files and evaluation methods.
- S9xxx Various service and maintenance contracts including re-validation services for the basic spectrometer system and extensions (e.g. external accessories).
- S905-OPVAL Extension of a maintenance or service contract by update to the latest OPUS release version and the System Validation Manual.

Bruker Optics is ISO 9001 and ISO 13485 certified.

Laser class 1 product.

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