



### OVP - Bravo PQ Protocol

Company: Bruker  
Operator: Bravo Bravo  
Instrument Type: Bravo Handheld  
Optics Configuration: Channel with: Lasers C-H & Fingerprint, Grating, Detector  
Accessory: None  
Instrument Serial Number: BRVXXXXX  
Instrument Firmware Version: 2.X  
OPUS/DB Version: OPUS 8 X/Build: 8, X/DB: 8, X  
Overall Test Result: PASSED  
Test expires: 12/15/202X, 11:56:12 AM (GMT+1)  
Test Date/Time: 12/14/202X, 11:56:12 AM (GMT+1)  
Test Spectra Path: C:\Users\Public\Documents\Bruker\OPUS\_8\_X\Validation\Data\202X1214\115612  
Date of last PQ Reference Measurement: 12/14/202X 11:53:21 AM  
Comment:

#### Wavelength Accuracy Test - Polystyrene\_Vial (Ph.Eur: 2.2.48, USP <888>, JP 2.26)

Ref. Peak (cm <sup>-1</sup> )	Allowed Dev. (cm <sup>-1</sup> )	Meas. Peak (cm <sup>-1</sup> )	Meas. Dev. (cm <sup>-1</sup> )
620.90	2.50	621.06	0.16
1001.40	2.00	1001.37	0.03
1602.30	3.00	1602.97	0.67
2852.40	3.00	2853.15	0.75

Overall Test Result = PASSED

Date and Signature

Date and Signature

## HANDHELD RAMAN SPECTROMETER

# System Validation - BRAVO

## Comprehensive compliance to pharmaceutical regulations

### Innovation with Integrity

The development and manufacturing of pharmaceutical products is subject to the strict rules of good laboratory practice. Bruker offers comprehensive system qualification that provides the documentation and procedures needed to use handheld RAMAN spectroscopy in compliance with the (c)GMP/GLP regulations.

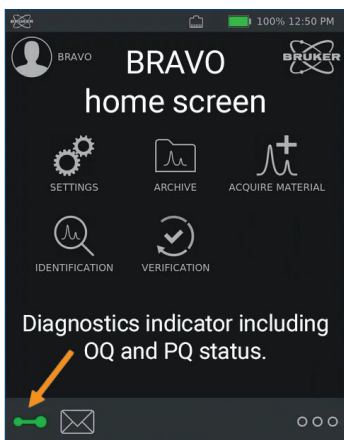
The handheld Raman spectrometer BRAVO shares the same meticulous validation concept as any other Bruker FT-IR/NIR or Raman spectrometer. The fully validated instrument software is flawlessly integrated to the validation concept of the OPUS spectroscopy suite to keep the cost of compliance at a minimum.

365 degrees of compliance starts with software being dedicated to the pharmaceutical industry, which leaves no room for breach of regulations. The validation option for Bruker's software solutions sets all in place:

- State-of-the-art user and signature management, with advanced access control.
- Sophisticated user rights concept to ensure SOD.
- 4-Eye-Principle electronic signatures.
- The use of released methods and spectra as well as valid performance tests are enforced.
- Protected Data Pool for secure electronic records and software configuration.

### A Validated Solution

- Fully automated OQ & PQ testing according to Ph.Eur., USP and JP requirements.
- Compliant to latest Data Integrity guidance by FDA.
- 21 CFR part 11 compliant electronic records and signature management.
- State of the art user management following the concept of segregation of duties (SOD).
- Comprehensive Audit Trails.
- System Validation Manual to support and document the qualification process.
- System qualification by certified service engineers.



## Performance Qualification – USP <858> & <1858>, Ph.Eur. 2.2.48

With BRAVO Bruker challenges current regulations setting a new benchmark for handheld Raman instruments being operated in the Pharmaceutical industry. Chapters Ph.Eur. 2.2.48 and USP <858> of the European and United States Pharmacopeia define minimum performance specifications for Raman instrumentation, respectively. Chapter 2.2.48 of the European Pharmacopeia 8.7 for the first time did consider specifically handheld Raman analyzers, and as well USP did introduce with chapter <858> explicit acceptance limits for wavenumber accuracy.

The optics of BRAVO have been designed to achieve highest standards in accuracy, being even capable to match the tighter performance limits set for benchtop equipment (P.Eur.), or quantitative analysis (USP). Routine Performance Qualification via the OPUS Validation Program OVP considers all individual requirements set by Pharmaceutical regulations, complemented by additional test procedures.

## Data Integrity

Data Integrity is a very important aspect especially as nowadays electronic records become established. OPUS and BRAVO strictly follow the ALCOA plus principle, considering all attributes which valid data should comply to. A mobile device might not provide secure data storage. However, BRAVO's Sync Service ensures that electronic records on device are transferred at first occasion to the Protected Data Pool – the OPUS solution for secure electronic records.

## Ready to Use System Qualification

The manifold aspects of instrument qualification is offered for BRAVO as a single package, ready to use upon installation, with minimum efforts upfront. The System Validation and Qualification Package (S011) comprises:

- Validation package for (c)GMP/GLP compliance of OPUS and BRAVO considering 21 CFR Part 11 (electronic signatures/ records) and Data Integrity aspects, along with a dedicated user management.
- Certified reference materials according to ASTM E1840, USP <858> & <1858> and Ph.Eur. 2.2.48 for comprehensive performance testing. Polystyrene reference certified traceable to NIST 1921b.
- System Validation Manual.

## System Validation Manual

The Bruker System Validation Manual forms the profound base of instrument qualification. It covers all regulatory requirements from Design (DQ), Installation (IQ), Operational (OQ) to Performance Qualification (PQ) and includes software release documentation and certification, compliance certificates, ready to use log forms to document and guide step-by-step the instrument qualification and many more.

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**Bruker Optics is ISO 9001, ISO 13485,  
ISO 14001 and ISO 50001 certified.**

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