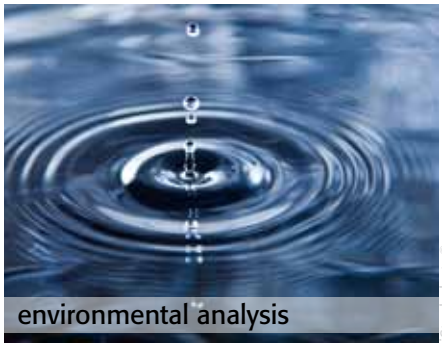
multi N/C®

analytikjena

Software, Compliance & Services


pharmacy

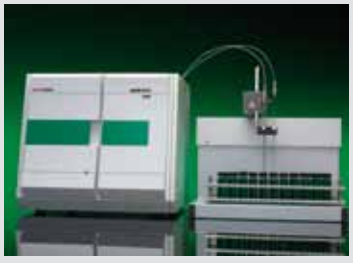

environmental analysis


semiconductor industry


multi N/C® 2100


multi N/C® 3100


multi N/C® UV HS


multi N/C® pharma

Quality assurance and GLP

GLP-compliant working requires complete documentation and traceability of the analysis results together with monitoring their quality. The software multiWin® comfortably supports you in this task.

multiWin® - software

- Intuitive software navigation
- Monitoring and control of all relevant system parameters
- Monitoring the system performance and analysis quality
- Comprehensive user-oriented functions, e.g. various calibration options including automatic calibration curve selection, blank value correction, recalculation of results, statistics
- Freely editable sample data also during the measurement
- Comfortable management and storage of the measured data and parameters
- Automatic or manual data export (LIMS, Excel)
- Clear, well arranged display of the measuring results in individual analysis reports
- User administration & management, audit trail and electronic signatures in accordance with FDA 21 CFR part 11

FDA 21 CFR Part 11 compliance

- All measured data (including raw data), method configurations and calibration data are stored in a database
- Complete traceability of data is possible at any time
- Useful filter functions support the search for specific database entries
- Older measuring data can be removed from the database and quickly made readable again

multi N/C® – Software, Compliance & Services

- Encrypted data safely prevent subsequent data manipulation
- User hierarchy, audit trail and electronic signatures
- User management with individual password allocation/administration and individually defined access rights for several users
- Complete recording of all events in the audit trail (login, logout, user handover, measurements, calibrations, messages generated by the self check system etc.) – manipulation is precluded
- Creation, verification and release of measuring data via electronic signature

Pharmaceutical applications – SST and more

- multiWin® software specifically adapted to the requirements of the pharmaceutical industry
- Requirements of individual pharmacopoeias (e.g. European pharmacopoeia < 2.2.44>, USP <643>) are supported by multiWin®
- System Suitability Test (SST) is an integrated function of the software user interface, guiding the user intuitively; results are issued as SST reports and stored in the audit trail
- Data manipulation by subsequent editing of measuring data is precluded since the data are stored in encrypted form
- Meets all requirements of FDA 21 CFR Part 11
- Special software is available for multi N/C® pharma systems

Services – qualification and validation

Analytik Jena supports you in the qualification and validation of your devices, methods and processes. We not only provide you with comprehensive documents for this purpose, such as installation qualification (IQ) and operation qualification (OQ). The user can also have these services performed by our trained specialist personnel.

In doing so we guarantee a high reliability of the accuracy and reproducibility of your measurements.

Recommendations

Software options	PC software multiWin®: for multi N/C® 2100/S, 3100, UV HS (already included in the scope of delivery of the devices)
	Standalone software multiWin®: for multi N/C® 2100S, 3100 (touch screen operation, included in the scope of delivery of the standalone option), data export functions and recalculation of results are not available in this version
	PC software multiWin® for pharmaceutical applications for : für multi N/C® pharma HT and multi N/C® pharma UV
Services	- device installation, commissioning and training for all devices of the multi N/C® series - installation with qualification and validation for multi N/C® pharma - training in application methods in Jena - on-site training in application methods at the user's premises - device maintenance - device maintenance with requalification
Documents	- guidelines for installation qualification (IQ) - guidelines for operational qualification (IQ) - guidelines for performance qualification (PQ) ...

Analytik Jena AG
Konrad-Zuse-Str. 1
07745 Jena/Germany

Phone +49/36 41-77 70
Fax +49/36 41-77 92 79

info@analytik-jena.com
www.analytik-jena.com

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