

KRÜSS LabGuide

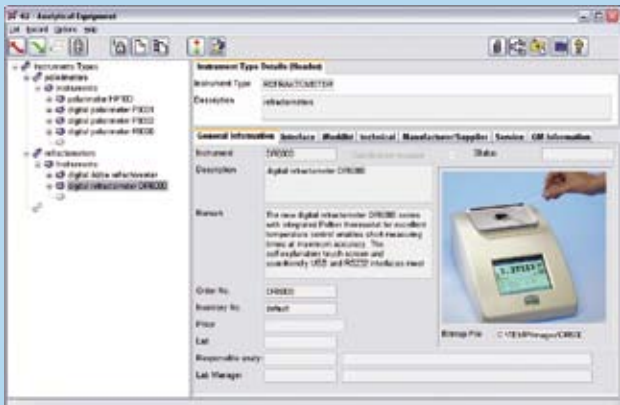
The program KRÜSS-LabGuide makes it easy for the laboratory technician to carry out measuring processes and find related documentations and values. It replaces the current manual records in the form of electronic journals. All requirements in handling electronic records and electronic signatures (ER/ES) are met by the KRÜSS-LabGuide according to 21 CFR Part 11. The development of the KRÜSS-LabGuide represents a collaborative effort between A. KRÜSS Optronic GmbH and iCD.GmbH on the basis of Laboratory Information/Management-Systems (LIMS) LABS/Q. Established 1796, A.KRÜSS Optronic in Hamburg, Germany has been developing and producing high precision optical measuring instruments for more than two centuries, now featuring state-of-the-art electronics.

iCD GmbH specializes in the development of software and related consultations for laboratories in the processing industry, government agencies and for energy and water supply enterprises.

KRÜSS-LabGuide software is delivered with the new generation of equipment for digital polarimeters and refractometers. It is our aim to fulfill the particular requirements for documentation and data security serving the pharmaceutical industry. Aside from a multi-lingual user guide, the system also includes a standardized interface for data exchange with other systems. A certified interface for SAP-QM is available as optional equipment.

User Management

The program includes a user management feature. Each user is assigned to a group through which he will be assigned access rights. Selection of the language version may be made during the registration process. All actions are recorded in an audit trail according to the requirements specified in 21 CFR Part 11.



Measuring Device Management

The supported laboratory devices are connected with each other via ethernet interface. The units will be automatically registered with KRÜSS-LabGuide and are available to the User for measuring- and test purposes.

Management of Measuring Methods

On the basis of prepared measuring methods for polarimeters and refractometers the User may set up and manage his own measuring methods with product-specific marginal values.

Evaluation and Reporting

Aside from the statistical print-outs of the recorded test data, the User has available to him various pre-established reports to print out results and test data. Individual reports may be obtained via external reporting tools with the use of a standardized data bank interface.



Scalability

LabGuide is a data bank based program. It may be used at an individual work station together with a test device, as well as in a network as an intranet application with several test devices and a central data bank.

Interfaces

Aside from the standardized XML-Interface used to exchange measuring data between LabGuide and other systems, the system offers data exchange with SAP-QM over a certified interface, as an optional feature.

The screenshot shows a 'Submission Report' from KRUSS LABORATORY. It includes a table with columns for 'Submission', 'Sample', 'Batch', 'Sample Size', 'Sample Point', and 'Regulation of Aspartic and Salylic acid'. The table contains data for multiple submissions and a summary row for 'Avg', 'Max', and 'Min' values.

Submission	Sample	Batch	Sample Size	Sample Point	Regulation of Aspartic acid % base	Regulation of Salylic acid % base
21000-01	241	01100000010-200	20.00	AS0101	21.7	2.10
21000-02	241	01100000010-200	20.00	AS0102	21.8	2.10
21000-03	241	01100000010-200	20.00	AS0103	21.9	1.90
Avg					21.8	2.10
Max					22.7	1.90
Min					21.6	1.90
Reg. F. Value					21.7	4.12
Index					1.88	3.764

Expandability:

LabGuide may be expanded through a variety of modules, beginning with the connection to other units such as analysis scales, via the management of test devices all the way to a complete, high performance Laboratory Information/Management System (LIMS).