Modular-Lab Analytical Equipment

For analytical HPLC of radioactive substances

Modular-Lab Standard and Modular-Lab PharmTracer provide the ideal platform for the research and production of radioactive substances. The extension of these systems with the Modular-Lab analytical HPLC Module makes the quality control of the produced agents possible with the same control unit using the same software.

Description

The laboratory equipment Modular-Lab Standard and Modular-Lab PharmTracer have been specifically designed to allow the production of a variety of radiotracers. Nevertheless the quality control of the products has to be performed on other equipment that has to be tested, qualified and validated for each application. Existing systems can instead be upgraded with the Modular-Lab analytical HPLC Module. The analysis by HPLC separation and detection of activity and UV-signal allows this part of the quality control to be performed on the Modular-Lab platform technology with the same control unit, PC and software as the synthesizer.

With its own control unit and PC the analytical HPLC Module can also be used independently from the synthesis system as a stand-alone device. The system is easy to operate and pre-validated processes are available for many applications or can be freely programmed by the user. The basic system runs isocratic HPLC analysis. A second pump allows a gradient HPLC profile. In a standard setup i.e. for the detection of radioactive labeled DOTA-conjugated peptides the analytical HPLC system consists of a HPLC Module (with injection valve, shielded activity detector, holder for column), a Knauer AZURA pump 4.1S (second for gradient), a Knauer UV detector UVD 2.1S, a Knauer HPLC Online-Degasser, a HPLC-column and all tubing and connectors as well as a control unit. The system will be installed and tested with the application intended. Operators will be trained and optionally an on-site performance qualification of a defined analytical process can be done. For evaluation of data a software tool for background correction, peak analysis and graph fitting is available. Data are compiled into tables and a report can be generated.

Advantages

The Modular-Lab analytical HPLC Module can be directly connected to any system of the Modular-Lab product family for an easy and low-cost possibility of HPLC-analysis. The analysis processes are programmed and tested by Eckert & Ziegler Eurotope GmbH.

The multifunctionality of the system allows routine analysis for PET tracers based on positron emitting nuclides as well as beta emitting nuclides. For many tracers a ready-to-go operating routine is available, but customized solutions for your analytical problems can be developed as well.

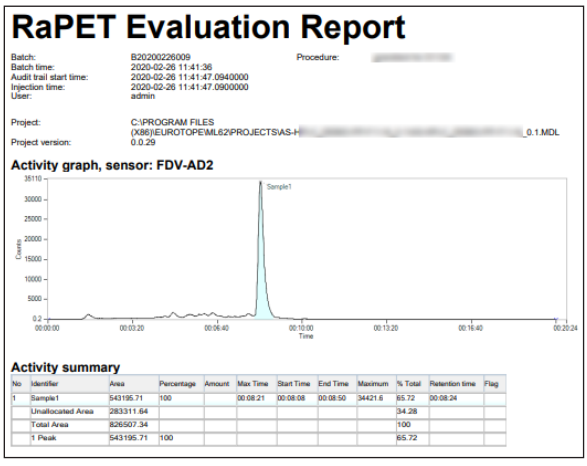
Software

The Modular-Lab Software has an intuitive user interface, is easy to program and adhering to today's regulatory requirements. Parameters such as pressure, activity detector readings, flow rates, UV-absorption or other parameters can be monitored within the interface.

Reports containing all relevant data and information are generated automatically after each run.

Quality Management

Eckert & Ziegler Eurotope GmbH works with a Quality Management System according to DIN EN ISO 9001 standard.



RaPET Evaluation Report

Batch: B20200226009 Procedure:
Batch time: 2020-02-26 11:41:36
Audit trail start time: 2020-02-26 11:41:47.0940000
Injection time: 2020-02-26 11:41:47.0900000
User: admin

Project: C:\PROGRAM FILES (X86)\EUROTOPE\ML62\PROJECTS\AS-H[redacted]0.1.MDL
Project version: 0.0.29

Activity graph, sensor: FDV-AD2

Activity summary

No	Identifier	Area	Percentage	Amount	Max Time	Start Time	End Time	Maximum	% Total	Retention time	Flag
1	Sample1	543195.71	100		00:08:21	00:08:08	00:08:50	34421.6	65.72	00:08:24	
	Unallocated Area	283311.64							34.28		
	Total Area	826507.34							100		
	1 Peak	543195.71	100						65.72		

HPLC Batch Report

Eckert & Ziegler

Modular-Lab Analytical Equipment

Technical Data

Module Characteristics	
HPLC Module with activity detector	Dimensions incl. handles: 130 x 188 x 192 mm (W x D x H), 3.6 kg With 6-Port/2-Position injection and switching valve; Port-to-port switching time: < 150 ms; (integrated into the HPLC Module)
Knauer AZURA P 4.1S (pump)	Dimensions: 113 x 135 x 225 mm (W x H x D), 1.5 kg Delivery system: Double-piston pump with working and auxiliary piston; Maximum operating pressure: 400 bar; Flow range: 0.001 – 10 ml/min; Flow rate accuracy: ± 1 %; Flow rate precision: < 0,5 % RSD
Knauer AZURA UVD 2.1S (UV detector)	Dimensions: 121 x 129 x 187 mm (W x D x H), 1.5 kg Wavelength: 190 - 500 nm; Wavelength precision: 0.7 nm; Wavelength accuracy: ± 3 nm, Light source: Deuterium (D2) lamp with integrated GLP chip; Noise: ± 2.0 x 10^{-5} AU at 254 nm; Drift: 3.0 x 10^{-4} AU/h at 254 nm; Control: analogue: ± 2.5 V scalable, 20 bit, digital: LAN-DHCP, RS-232, remote connector
Knauer AZURA DG 2.1S (Degasser)	Dimensions: 121 x 138 x 190 mm (W x D x H), 2.3 kg Degasser channels: 2; max. flow rate: up to 10 ml/min; Degassing method: Gas permeation through a fluoropolymer membrane; Dead volume: Approx. 285 µl per channel; Solvent applicability: Universal, except hydrochloric acid, halogenated hydrocarbons, hexafluoro isopropanol (HFIP), hexane, heptane
HPLC-Column	Pre-column and different analytical columns are available according to application or upon request
Main Unit (electrical cabinet only needed for 'stand-alone' system)	
Power supply (for electrical cabinet)	115 V ~ 60 Hz or 230 V ~ 50 Hz
Power consumption (electrical cabinet)	Standard 480 W, 2 x BUS 1,050 W, extension to 2,100 W possible
Environment temperature	+10 °C to +40 °C
Environment humidity	Max. 70 % rel.
Unit Control	
Software	Modular-Lab Software
Interfaces	Ethernet

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