SARTORIUS

Product Datasheet

PATfix® AAV Platform

Orthogonal Solution for AAV Analysis in Process Development

Product Overview

The production of adeno-associated virus (AAV) viral vectors is a complex, lengthy, and often expensive process that necessitates purifying AAV preparations to remove process—and product-related impurities. Furthermore, it requires implementation of analytical techniques to monitor the process throughout the development and manufacturing phases.

The PATfix® AAV platform offers comprehensive analysis and control of the downstream purification process (DSP) samples, ensuring improved efficacy, safety, and purity of the final viral vector products. By monitoring key parameters such as recoveries, impurities, and the full/empty ratio, this tool enables rapid analytics starting at 8 minutes per sample. The PATfix AAV Platform employs straightforward chromatographic conditions compatible with routine laboratory workflow, requiring minimal sample preparation, decreasing variability and potential errors.

Features | Benefits

- **All-in-One Solution**: The PATfix® AAV platform integrates multiple analytical outputs into a single platform, streamlining the process and reducing the need for separate assays.
- **Impurities Detection**: Utilizes size exclusion chromatography (SEC) to monitor DSP samples for protein, DNA, and aggregate impurities, enhancing process validation and quality control.
- **Total Recovery**: Employs cation exchange chromatography (CEX) for serotype-independent recovery and determination of total AAV capsids, providing reliable tools for process optimization.
- **Process Development**: Represents an initial method using CIMac QA HR column to establish a separation and identification of AAV capsids, providing estimation of full AAV, assessing their heterogeneity and improving product quality regardless of AAV serotype.
- **AAV8 Product Purity**: Enables efficient separation and quantification of AAV8 capsids using CIMac QA HR column, ensuring high purity levels.
- **User-Friendly Software**: Fully compliant with GDP 21 Part 11, ensuring ease of use and regulatory adherence.
- **Future-Ready**: Platform designed for future enhancements at no additional cost, ensuring long-term value.

Introduction

Platform Overview

The PATfix LC analytical system performs multiple analyses, facilitating continuous at-line analytics to enhance process development and quality control. The PATfix AAV platform simplifies analytical chromatography for non-experts, enabling fast integration for at-line analysis in process development.

The platform offers:
- The all-in-one analytical system features multiple detectors, including UV, conductivity, pH, and optionally MALS and FLD, controlled by PATfix software.
- Methods together with SOPs to run samples.
- The appropriate columns: CIMac or BIA SEC columns for AAV process development

CIMac analytical column included

Key parameters in DSP evaluation

Crude and purified samples

Impurities detection

Process recoveries

E/F separation product QC

The PATfix Software

The PATfix software is designed to simplify analytical chromatography for everyday operations while retaining the necessary detail and complexity for higher-level tasks. Key features include:
- **Information Extraction**: Handled via user-defined templates, allowing for tailored data analysis.
- **Data Visualization**: Accelerates progress during process development by providing clear and actionable insights.
- **Unified Database:** Creates a single database of chromatograms from multiple analytical systems, ensuring comprehensive data management.
- **Interactive Results Sharing**: Easily share results with colleagues, customers, and regulators, with report generation that eases the paperwork load.
- **Regulatory Compliance:** 21 CFR Part 11-compliant software with qualified methods according to FDA and EMA guidelines on analytical chromatography..

PATfix AAV Methods

The complexity of the AAV downstream process necessitates monitoring various aspects and DSP stages to ensure optimal performance and quality of the final product.

Currently, four AAV analytical methods are included in the PATfix AAV platform:
- Impurities Detection
- Total Recovery
- Process Development
- AAV8 Product Purity

The PATfix AAV methods include:
- Optimized and qualified analytical methods
- Guidelines for sample preparation and buffers (WO2024252024A1 and WO2025073922), as well as analysis and data processing described in SOPs

Analytical Columns

BIA SEC Methacrylate-2000A: Monitoring Impurities in AAV Samples
The BIA SEC Methacrylate-2000A column utilizes size-exclusion chromatography to effectively separate and analyze large biomolecules. This column is specifically designed to monitor impurities such as proteins, DNA, and aggregates in AAV samples.

Key Features:
- **Technology:** Constructed from methacrylate, ensuring durability and stability for consistent analytical performance.
- **Application:** Ideal for separating components based on size, providing detailed insights into the purity and composition of AAV samples.
- **Functionality:** Enables precise monitoring and characterization of impurities, supporting robust process development and quality control in AAV production.

CIMac SO3 Column: Total Capsid Recovery in AAV Production
The CIMac SO3 column is a critical component of the PATfix AAV platform, utilizing cation exchange chromatography to facilitate the recovery and determination of total AAV capsids during downstream processing (DSP).

Key Features:
- **Technology:** Employs cation exchange chromatography, leveraging ionic interactions to separate AAV capsids from negatively charged impurities.
- **Application:** Designed for serotype-independent recovery, providing a reliable tool for process optimization and quality control in AAV manufacturing.
- **Functionality:** Enables precise quantification and recovery of AAV capsids, ensuring robust performance throughout the purification process.

CIMac QA HR Column: Process Development and Product Purity
The CIMac QA HR utilizes advanced reproducibility in chromatography techniques, enabling efficient separation and precise quantification of AAV capsids, particularly focusing on purity.

Key Features:
- **Technology:**Employs high-resolution chromatography to achieve detailed separation and analysis of AAV capsids
- **Application**: Specifically designed for the Product purity method, ensuring the efficient separation and quantification of AAV8 capsids.
- **Functionality**: Provides accurate assessment of capsid purity, supporting robust quality control and process development.

PATfix System Hardware

Setting up the appropriate hardware for effective and consistent analytical separation of large biomolecules in the AAV DSP is complex. AAV mixtures consist of the target AAV subspecies, along with process-related impurities (such as genomic DNA, proteins, and aggregates) and product-related impurities, all of which have similar biophysical characteristics that make precise detection challenging. Conductivity and pH monitoring enhance in-process robustness, ensuring consistent and reliable performance.

The PATfix AAV platform includes the hardware listed below to perform the required analyses.

Pump
The low-pressure gradient pump, equipped with an integrated degasser and mixer, features bio-inert ceramic pump heads. Quaternary buffer switching enables analytical methods with included cleaning in place (CIP) and column regeneration, ensuring robust performance.

Conductivity | pH Monitor
A contactless conductivity probe with a wide measuring range enables in-process monitoring of salt concentration gradients and facilitates tracking complex methods, including pH gradients.

Autosampler
The autosampler accommodates vials or microtiter plates. An automated needle wash ensures minimal carryover, while temperature control of the sample tray secures sample stability while waiting for analysis.

Column Thermostat
The column thermostat ensures additional robustness by reducing the risk of environmental temperature fluctuations affecting experimental outcomes and enables operation at temperatures ranging from 5 to 85 °C.

Multi-Wavelength UV Detector
Highly sensitive monitoring of up to 4 wavelengths in the 190–700 nm range is possible, while intelligent temperature control minimizes drift. It helps to detect impurity proteins and nucleic acids.

Fluorescence Detector (Optional)
A fluorescence detector is key to determining proteins with intrinsic tryptophan fluorescence for process development tasks based on innovative or challenging nucleic acid samples that require additional characterization. At the same time, PicoGreen FLD allows for identifying DNA impurities, such as host cell (hc) DNA.

MALS Detector (Optional)
Suitable for particle characterization like AAV particles, including aggregates and complexes. It effectively identifies AAV capsids in complex samples, distinguishing them from aggregates, DNA, and protein impurities. Therefore, the MALS signal can be used in recovery calculations.

Figure 1: *Analytical Columns*

BIA SEC analytical column

CIMac SO3 analytical column

CIMac QA HR analytical column

Relevant Application

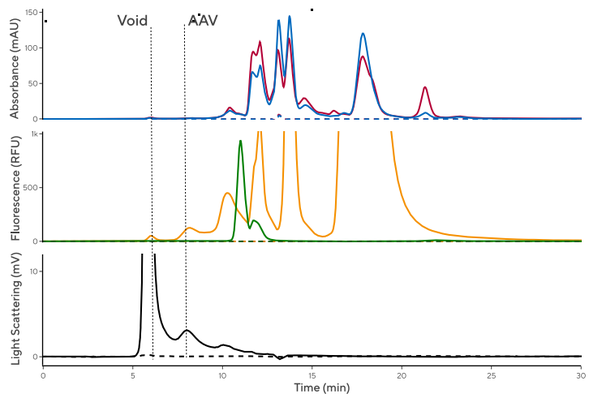
Impurities Detection Using BIA SEC Column

The PATfix Impurities detection method is specifically designed to qualitatively monitor DSP of AAV samples by determining the presence of protein, DNA, and aggregated impurities. This technique uses size exclusion chromatography (SEC) to analyze DSP samples.

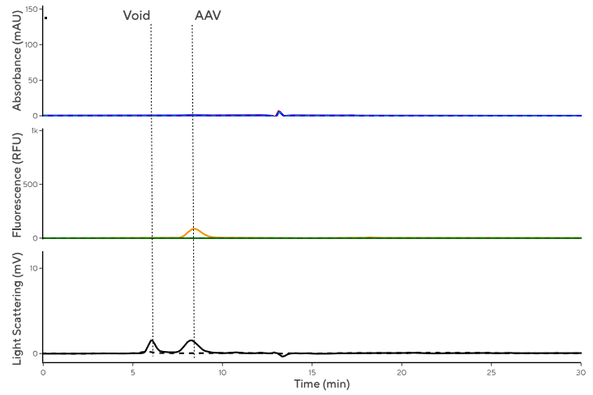
Challenge Addressed:
Determining the size distribution and detecting aggregates, host cell proteins, DNA, or monitoring of process impurities.

Solution:
Determining the size distribution and detecting aggregates, host cell proteins, DNA, or monitoring of process impurities.

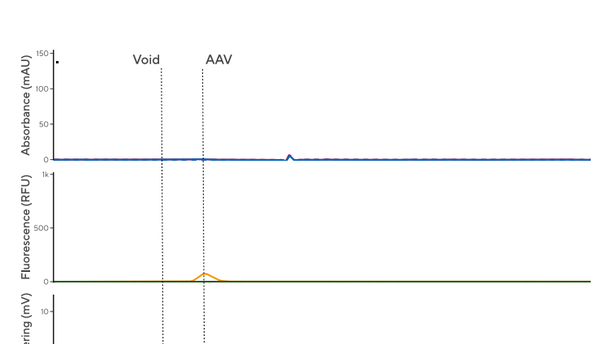
Figure 2: *Example Chromatogram Showing Impurities Reduction During DSP*



A) Harvest AAV8 sample



B) TFF retentate AAV8



C) Pre-purified AAV8, all analyzed on a BIA SEC Methacrylate-2000A column and monitored by triple detectors

Figure 2 shows a chromatogram of different DSP samples obtained using a BIA SEC Methacrylate-2000A column. Key peaks include:

- Void peak at approximately 6 minutes
- AAV8 capsid peak at approximately 8 minutes
- Impurities eluting from 9 minutes onward

The PATfix method demonstrates a reduction in aggregates, which can be assessed with a MALS detector. It provides several signal outputs, enhancing the understanding of each chromatographic run.

AAV Total Recovery Monitoring Using CIMac SO3

The Total Virus Capsids method is a cation exchange chromatography (CEX) technique designed to recover and determine total AAV capsids during DSP. It applies to multiple serotypes, and this serotype-independent method provides a reliable tool for process optimization and ensuring quality control in AAV manufacturing.

Challenge Addressed:
How to quickly determine recoveries during the DSPs despite the challenges posed by impurities.

Solution:
The PATfix Total Recovery method identifies DSP inefficiencies by tracking AAV recovery percentages and optimizing processes for maximum yield through multi-detector capabilities. This method applies to various AAV serotypes.

Figure 3: *The chromatogram of multiple signals (UV, FLD, MALS) for the AAV8 harvest (represented by the light line) and the standard AAV8 capture eluate sample (indicated by the bold line).*

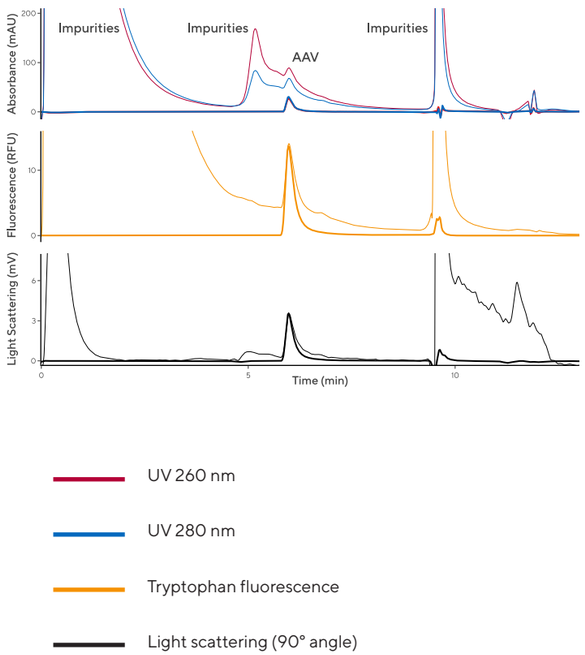


Figure 3 displays the chromatogram signals (UV, FLD, MALS) for AAV8 harvest (light line) and standard AAV8 capture eluate (bold line). The MALS detector effectively identifies AAV capsids, distinguishing them from DNA and protein impurities. The overlapping MALS peaks in both samples highlight consistent detection.

Figure 4: *The MALS chromatogram for different AAV serotypes. The MALS detector selectively identifies total AAV capsids and aggregates, filtering out smaller components like proteins. Enhanced by FLD and UV signals, this method aids in monitoring AAV DSP samples and assessing AAV recovery across various serotypes.*

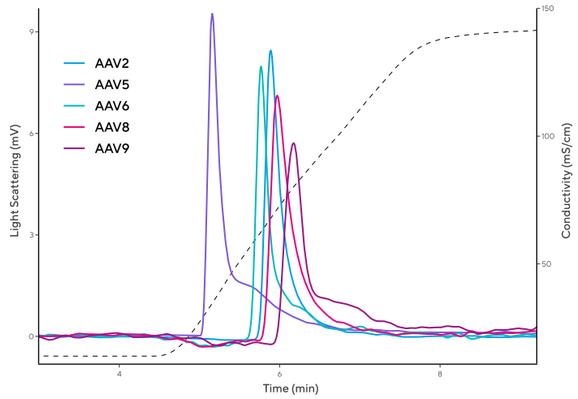


Figure 4 illustrates the SO3 method's applicability to diverse AAV serotypes. Total AAV capsids from five serotypes are eluted in the middle of a salt gradient (except for AAV5, which elutes slightly to the left), ensuring a robust recovery determination method that applies to various AAV serotypes.

Determination of Empty and Full AVVs Using CIMac QA HR

The AAV Empty and Full Process Development method utilizes a CIMac QA HR column to effectively develop empty-full processes to separate and identify various AAV capsids. This method provides a reliable tool for assessing AAV integrity and applies to multiple serotypes.

Challenge Addressed:
Estimating full AAV capsids and efficiently separating heterogeneous capsid populations. Applicable across different AAV serotypes. A foundational method suitable for empty-full process development on both analytical and preparative scales due to its scalability.

Solution:
The method's flexibility allows for fine-tuning parameters to improve resolution between empty and full AAV capsids for different serotypes or to distinguish additional capsid variants.

Figure 5: *An example chromatogram for AAV8 serotype analyzed by the AAV Process Development method. During DSP*

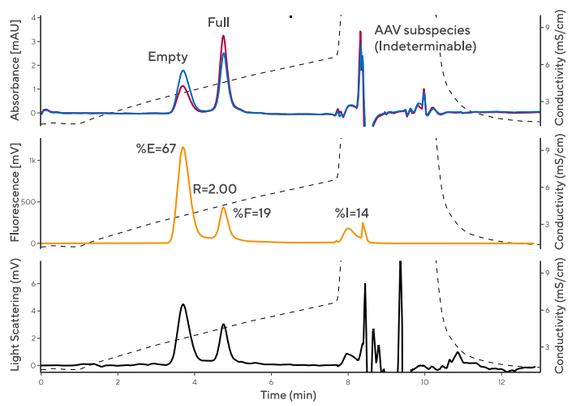


Figure 5 illustrates the example chromatogram for the AAV8 serotype using the AAV Process Development method. It achieves baseline separation (R=2.00) between the empty (E) and full (F) capsids. Indeterminable capsids (I), potentially overfilled or deaminated, elute later due to their higher electronegativity.

Figure 6: *An example chromatogram of a typical separation results showing four different AAV serotypes (AAV4, AAV5, AAV8 and AAV9) using unchanged Process Development method.*

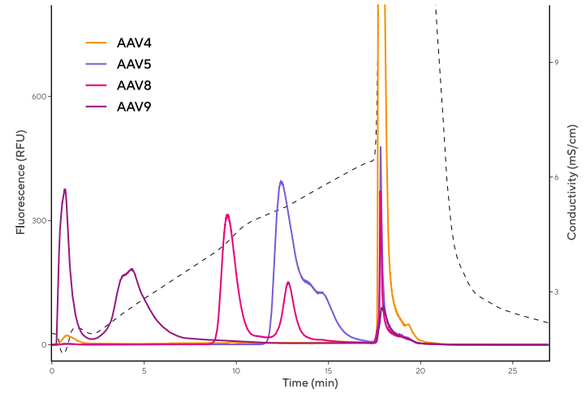


Figure 6 shows a foundation step in developing an improved separation of empty and full AAV capsids. A baseline separation of AAV capsids can be obtained by tuning the binding, elution salt, and pH. This method, therefore, represents an important foundation for later AAV serotype-specific methods for empty and full separation. In orange, a baseline separation of empty, full, and other AAV8 capsids is illustrated.

Method optimization typically involves fine-tuning current conditions. If the sample doesn't bind (e.g., elution of AAV9 empty capsids in flow-through as shown in Figure 5), optimize by decreasing loading buffer conductivity or increasing loading pH, shifting elution right. Conversely, if the sample strongly binds to the QA column (as with AAV4 in Figure 5), increase salt concentration during loading and/or elution. Lowering binding pH can also promote earlier elution, shifting the elution time left.

Quantification of Full AVV8 Using CIMac QA HR

The Product Purity Method employs a CIMac QA HR column to facilitate the efficient separation, precise quantification, and accurate content analysis of full AAV8 capsids.

Challenge Addressed:
Navigating the complexities of AAV8 sample variations while ensuring regulatory compliance.

Solution:
This serotype-specific method achieves efficient separation and quantification, validated according to EMA and FDA guidelines. It adapts seamlessly to diverse USP conditions, ensuring purity across various AAV8 samples.

The PATfix Product Purity AAV8, which utilizes the CIMac QA HR column, represents a precise and linear methodology for quantifying full capsids.

The AAV Product Purity method applies to various AAV8 samples, which differ in USP conditions, including cell line, transfection reagent, media, feed, and transfection duration.

Figure 7: *Various AAV8 samples analyzed by the Product Purity method. Sample 1 – 5.*

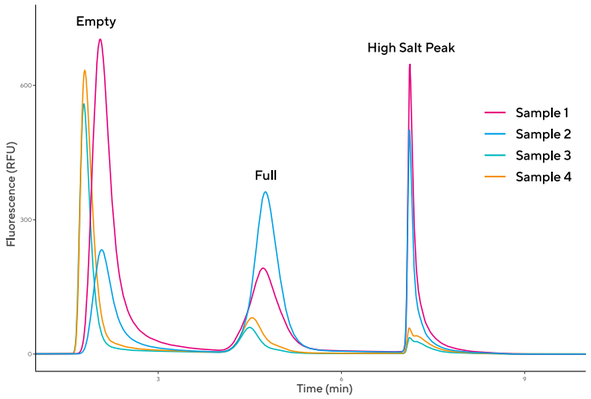


Figure 7 illustrates different AAV8 samples analyzed by the Product purity method. The separation between Empty, Full and High salt peaks were preserved in all tested samples. However, small shifts in retention times are observed due to the effect of different USP conditions on charge of AAV capsids.

Table 1: *Pre-purified AAV8 sample analyzed by different orthogonal methods. DGUC – density gradient ultracentrifugation, TEM – transmission electron microscopy, CD-MS – charge detection mass spectrometry, MP – mass photometry*

Orthogonal analytical method	% Full
PATfix AAV8 Product Purity	22
dPCR/ELISA	21
PATfix DGUC	22
quTEM	20
CD-MS	21
MP	32

The percentage of %F determined by the PATfix AAV8 Product Purity method corresponds closely with findings from various tested orthogonal techniques. Differences in the percentages of AAV capsids may arise due to the limited selectivity inherited in each method (e.g., Mass Photometry).

Hardware Components

UV Absorbance Detector

Detection	Description
Detector type	Multiwavelength detector
Detection channels	4 digital
Light source	Deuterium (D2) lamp with integrated GLP chip
Wavelength range	190–700 nm
Spectral bandwidth	< 8 nm at Hα line (FWHM) Note: digital bandwidth 1–32 nm
Wavelength accuracy	± 2 nm
Wavelength precision	0.1 nm
Wavelenght verification	Internal holmium filter and deuterium lines
Noise	± 30 µAU at 254 nm
Drift	1500 µAU/h at 254 nm
Linearity	> 1.6 AU at 274 nm, typically 2.5 AU
Time constants	0.00 | 0.01 | 0.02 | 0.05 | 0.10 | 0.20 | 0.50 | 1.00 | 2.00 | 5.00 | 10.00 s
Integration time	Automatic (5–1000 ms)

Communication	
Detector Interfaces	LAN (RJ-45), RS-232 (SUB-D 9), multi-pin connector, analog (RCA cinch connector)
Control	PATfix software
Inputs	Error (IN), Start (IN), Autozero, Event 1–2
Outputs	Error (OUT), +5 V, Valve +24 V, Valve (OUT), Start (OUT)
Analog outputs	1 x 0–5 V scalable, 20 bit, offset adjustable

Technical parameters	
GLP	Detailed report including lamp recognition, operating hours, lamp operating hours, number of lamp ignitions
Display	N/A
Ambient conditions	Temperature range 4–40 °C, 39.2–104 °F, humidity: below 90 %

General	
Power supply	100 – 240 V, 50 – 60 Hz, 75 W
Dimensions (W × H × D)	361 mm x 158 mm x 523 mm
Weight	12.2 kg
Leak sensor	Yes

Analytical Pressure-Proof UV Flow Cell Cartridge (For Aqueous and High Salt Condition)

Technical	
Path length	10 mm
Connection	1/16"
Volume	10 µL
Wetted parts	Titanium, Quartz, PEEK
Maximum flow rate	20 mL/min
Maximum pressure	300 bar

Pump

General information	
Variant	Quaternary low-pressure gradient pump
Delivery system	Dual-piston pump
Pulsation compensation	Active pressure and pulsation compensation
Pulsation	< 2 % Amplitude (typically: < 1.3 %) or 3 bar (0,3 MPa), whatever is greater, at 1 mL/min ethanol, at all pressures > 10 bar (1 MPa, 147 psi)
Flow rate range	0.01–10 mL/min 0.1–6 mL/min (recommended)
Flow rate increment	0.01 mL/min
Flow rate accuracy	< 1 % (measured at 5-80 % of flow range, using ethanol)
Flow rate precision	0.1 % RSD (based on the retention time at constant room temperature)
Flushing piston seal	Standard
Gradient range	0-100 %
Maximum delivery pressure	400 bar
System protection	Soft start, programable P_{max}
Wetted materials	Sapphire, ruby, ceramic, FKM

Degasser module	
Degasser channels	2 channels, Teflon® AF
Degasser max. flow rate	10 mL/min
Degasser method	Gas permeation using Teflon® AF amorphous fluoropolymer membrane
Degasser efficiency	< 0.5 ppm dissolved O_2 at 1 mL/min
Degassing chamber volume	480 µL volume per channel
Eluents	Limitations: THF, DMSO, hydrochloric acid and halogenated hydrocarbons, in particular hexafluoroiso-propanol (HFIP). Pump wetted materials are compatible with salt buffers and common organic solvents (ACN, MeOH, IPA and EtOH). Pump shouldn't be left in high concentration organic solvents and high salts for prolonged time.
Wetted materials	PEEK, Tefzel®, Teflon® AF
Vacuum pump	Low hysteresis

Communication	
Interfaces	LAN, Pin header connectors (Analog IN, Start IN, Error IN)
Control	PATfix Software
Analog input	0-10 V
Analog control input	Flow rate
Level | event outputs	8 event outputs (TTL, OC, Relays) and 24 V
GLP	RFID pump head detection, detailed report
Display	3 LEDs
Leak sensor	Yes
Protection type	IP-20

General	
Power supply	Power input: 100-240 V Output: 50-60 Hz Maximum power consumption: 100 Watt
Dimensions (W × H × D)	361 mm x 208.2 mm x 523 mm
Weight	12.7 kg
Leak sensor	Yes
Temperature range	4-40 °C (39.2-104 °F)
Air humidity	Below 90 %, non-condensing

Quaternary Low-Pressure Gradient

Setup	
Pump type	Quaternary analytical HPLC pump with degasser
Pump head	10 mL/min ceramic
Degasser	4 channels, Teflon® AF
Special feature	Automatic adaption of LPG cycle time
Weight	12.7 kg
Gradient type	Low-pressure gradient
Gradient range	0–100 % 1–99 % (recommended)
Minimum increment	1 %
Gradient precision	± 0.3 % (measured at 1 mL/min, 150 bar, tracer: ethanol/caffeine) ± 2 % (1–99 %, measured at 5-50% of the flow range, tracer: water/caffeine)
Gradient repeat accuracy	< 0.1 % RSD (measured at 1 mL/min, 0.5 % RSD overall, based on retention time at constant room temperature)
Mixing volume	250 µL (metal-free)
Delay volume	410 µL (metal-free)

10 mL Pump Head

General information	
Flow rate range	0.01 mL/min-10 mL/min 0.1-6 mL/min (recommended)
Maximum pressure	400 bar (40 MPa, 5800 psi) – ceramic

Autosampler

Sample injection	
Max. plate | vial height	47 mm (incl. septa or capmat)
Sample capacity	108 standard autosampler vials
Injection volume range	1-4999 µL (depending on loop and vial volume)
Sample loop	100 µL | 200 µL | 1000 uL
Dispenser syringe	250 µL
Headspace pressure	Built-in compressor, only for sample vials with septum
Switching time inj. valve	< 100 ms
Piercing needle precision	± 0.6 mm
Sample tray cooling	With cooling function 4 – 40 °C
Vial detection	Missing vial/well plate detection by sensor
Needle wash	Programmable: wash between injections and wash between vial
Wetted materials	Tefzel® (ETFE), Glass, Teflon® (PTFE), Kel-F® (PCTFE), stainless steel, PEEK
Injection modes	Full loop filling, partial loop filling and microliter pickup, PASATM (pressure-assisted sample aspiration)
Injection precision	RSD (Relative Standard Deviation): Full loop filling < 0.3 % Partial loop filling at injection volumes > 5 µL: < 0.5 % Microliter pickup at injection volumes > 5 µL: < 1.0 %
Sample carryover	<0.05 % with needle cleaning
Injections per vial	Max. 9 injections

Communication	
Interfaces	LAN, ANALOG
Control	Ethernet (LAN)
Inputs	2 programmable TTL inputs (next injection, freeze, stop)
Outputs	1 programmable relay output (inject marker, auxiliary, alarm)

General	
Power requirements	95 – 240 V AC +/- 10%, 50 - 60 Hz
Power consumption	200 VA
Dimensions (W × H × D)	364 × 379 × 623 mm
Weight	32 kg
Stackable weight (Maximum weight on top)	65 kg
Leak sensor	None
Ambient conditions	Temperature range: 10 – 40 °C; 50 – 104 °F Air humidity: 20 – 80 %

Conductivity Monitor

Detector type	Conductivity monitor
Conductivity	0.1–999 mS/cm
Accuracy	<5 % scale end value
Precision in measured range (0.1-300 mS/cm)	<2 % of full scale or ≤5 mS/cm for higher values
Linearity	±1 % scale end value
pH measured range	pH 2-12
pH precision	±0.2 pH in temperature range 4–25 °C
pH accuracy	±0.5 pH in temperature range 4–25 °C
pH drift	Maximum 0.02 pH/h at pH 4
Maximum data rate	5 Hz (LAN, RS-232, Analog)
Outputs	LAN, RS-232, Analog
Analog output	Conductivity, pH
Control	Manual: front panel
Protection type	IP 20
Temperature range	4 – 40 °C; 39.2 – 104 °F
Air humidity	Below 90%, non-condensing
Air pressure	84 – 106 kPa; 840 – 1060 mbar
Power supply	100-240 V, 50-60 Hz, max. 20 W
Dimensions (W × H × D)	121 x 129 x 187 mm
Weight	3.2 kg

pH Measuring Kit

Maximum flow rate	80 mL/min
Delay volume	80 µL

Conductivity Flow Cell, Analytical

Flow cell type	Conductivity flow cell
Biocompatible	Yes
Fiber optics version	No
Capillary connection	1/16"
Wetted materials	PEEK
Flow cell volume	30 µL
Maximum flow rate	10 mL/min
Maximum pressure	160 bar

Optional Fluorescence Detector

General information	
Light source	Xenon lamp
Wavelength range	200 to 650 nm
Spectral bandwidth	20 nm
Wavelength accuracy	2 nm
Wavelength reproducibility	0.2 nm
S/N	Water Raman peak S/N 1200 min.
Cell (capacity, pressure resistance, material)	12 µL; 2 MPa (approx. 20 kgf/cm2); SUS316L, PTFE (fluororesin), quartz
Simultaneous Monitoring of Wavelengths	Measured wavelength: Any two wavelengths between 200 and 650 nm Sampling period: 0.5 s per wavelength
Operational ambient temperature range	4 to 35 °C
Dimensions (W × H × D)	260 × 420 × 210 mm
Weight	16 kg

Optional MALS Detector

Sample injection	
Sample cell volume	63 µL
Pressure stability	Up to 10 bar
Light scattering volume	< 7.8 nL
Wetted parts	Glass, PTFE + 25 % carbon, stainless steel, titan
Solvent compatibility	Aqueous and organic solvents with the same flow cell
Light scattering angles	28° – 156° at 9 angles 0 – 4 V at 24 bit 0.24 µV resolution
Signal processing	DSP on every single photo detector, different filter algorithms possible
Molar mass range	103 to 109 Da depending on sample
Radius of gyration range	Approx. 8 nm to 250 nm depending on sample
Laser specifications	630 nm (red)
Laser life time	Approx. 10.000 hours
Safety functions	Vapor sensor Leak sensor
Cell temperature control	10 °C above room temperature Up to 60 °C Stability +/- 0.01 °C at 35 °C
Power requirements	100 – 240 V @ 50 – 60 Hz, 155 W, universal power input
Electronic inputs | outputs	Error in/out, injection ready in/out, ethernet interface
Environmental conditions	20 – 80 % relative humidity (noncondensing) at an ambient temperature range of 4 – 30 °C (*) (*) When the laser is activated above 10 °C
Dimensions (W × H × D)	46 cm x 26 cm x 16 cm
Shipping weight	17 kg

Software

Software name	PATfix®
Version	2.1.24050
Compliance	21 CFR Part 11
License	Perpetual, per system
System architecture	.NET Framework
Operating system	Windows 11/10
Database	SQLite
Display language	English
Client | server	Client | server functionality
Supported instruments	Detector MWD 2.1 Detector MALS 3601/3609 Detector RF-20A Interface box IFU 2.1 Autosampler AS 6.1L Pump P 2.1S/P 4.1S Pump P 6.1L LPG Pump P 6.1L HPG Monitor CM 2.1S/pH 2.1S
Instrument connection	RS-232, Ethernet, USB
Recommended PC hardware	Memory: minimum 4 GB, recommended 8 GB CPU: minimum 1 CPU core @ 2 GHz speed, multi-core CPU recommended Onboard (integrated) graphics 256 GB for installation and data storage, SSD is highly recommended Monitor: minimum 1680 × 768, recommended 1920 x 1080
Chromatography definitions	European Pharmacopeia (EP)
Security	SSL certificate (optional)
Authentication	Local (integrated), Domain (optional)
Max. number of users	No restrictions
Setup format	MSI installer
Main features	Instrument control, integration, calibration, templates, reports, peak fitting, radius calculation, method revision history
Data export	CSV
Operation	Sequence or manual run

AAV Platform

AAV Impurities Detection

Column chemistry	SEC Methacrylate-2000A
Method	Qualitative
Attribute	AAV Proteins, DNA/RNA Impurities Aggregates and Complexes

Total Viral Capsids

Column chemistry	SO3
Method	Qualitative
Attribute	Total AAV capsids

The Empty and Full Process Development

Column chemistry	QA HR
Method	Qualitative
Attribute	E/F ratio and full capsid titer estimation

AAV Product Purity

Column chemistry	QA HR
Method	Qualitative and Quantitative
Attribute	E/F ratio and full capsid titer estimation
LOQ	LOQ = 1.5E+09 vg/mL
Linearity Range	5E+09 – 5E+10 vg/mL
Precision	RSD < 15%, According to EP and FDA guidelines.
Accuracy	RSD < 15%, According to EP and FDA guidelines.

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