SARTORIUS

Product Datasheet

PATfix® AAV Switcher Platform

Orthogonal Solution for AAV Upstream Process Monitoring

Product Overview

Upstream processes (USPs) for producing adeno-associated virus (AAV) vectors are complex and costly, requiring accurate analytical techniques for effective process monitoring and optimization. A precise evaluation of upstream samples is essential but challenging due to the presence of diverse impurities and high variability in analytical measurements.

The PATfix® AAV Switcher Platform is an advanced analytical solution that leverages established liquid chromatography techniques to provide a comprehensive analysis and control of USP samples.

It enables accurate estimation of the final viral vector quality, including critical parameters such as the percentage of full AAV capsids. Designed for easy integration into routine laboratory workflows, the PATfix AAV Switcher Platform reduces sample preparation steps, minimizes variability, and lowers the risk of errors, thus supporting reliable and efficient upstream process monitoring. Unlike some other complementary analytical methods for USP monitoring, which combine multiple techniques (e.g., ELISA, PCR) to estimate the full capsids or require pre-purified samples to minimize matrix effects, the PATfix AAV Switcher Platform allows for faster throughput analysis and quicker USP optimization.

Features | Benefits

- **All-in-One Solution**: The PATfix AAV Switcher Platform integrates two chromatographic steps and multiple analytical outputs into a single run, streamlining the process and reducing the need for separate assays. This enables a direct characterization of complex USP samples without the need for pre-purification or multistep approaches.
- **Process Monitoring and Process Optimization**: The PATfix AAV Switcher enables comprehensive monitoring and optimization of USPs in terms of process timing, preventing impurity buildup and maximizing system productivity.
- **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

PATfix AAV Switcher Platform Overview

The PATfix® LC analytical system performs continuous at-line analytics to enhance USP monitoring and development. It simplifies analytical chromatography for non-experts, enabling fast integration for at-line analysis of complex USP samples.

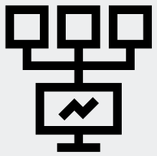
The PATfix AAV Switcher Platform offers:
- The all-in-one analytical system features multiple detectors, including UV-Vis detector, conductivity, pH, multi-angle light scattering (MALS) and optional fluorescence detector.
- Methods together with SOPs to run samples.
- The appropriate columns: CIM® and CIMac columns for AAV USP monitoring

CIMac analytical columns

Tandem 2D chromatography

Handle USP samples effectively

Capture and separation step



Multidetector setup (FLD, UV, MALS)

E/F separation, with the percentage of full capsids

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 detailed 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 AAV8 Switcher Method

The complexity of the AAV upstream process requires reliable analytical methods to monitor USP are required for optimal performance of USP.

Many analytical tools commonly used for complex samples require a certain level of purity and concentration to produce reliable results. For upstream samples, this often means adding a sample preparation step, which can take as much time as the analysis itself. Additionally, if the preparation process is not robust, it can introduce variability and uncertainty into the results. To address these challenges, we developed the PATfix AAV Switcher Platform, which minimizes sample preparation by simply diluting and clarifying the sample while incorporating purification and concentration steps directly into the method. The first stage of the AAV8 Switcher method relies on a universal and highly robust AAV capture process. The analysis then proceeds to the second stage, which allows for the baseline separation of different AAV capsid populations, ensuring accurate sample characterization.

Incorporated methods in the PATfixAAV Switcher Platform:
- **CIM Trap SO3 pre-purification and capture:** Utilizes cation exchange chromatography for initial in-line sample purification and concentration.
- **CIMac QA HR empty-full separation:** Provides detailed separation and analysis of AAV capsids.

The PATfix AAV8 Switcher method include:

- Optimized and qualified analytical methods
- Guidelines for sample preparation and buffers (WO2024252024A1), as well as analysis and data processing described in SOPs

Analytical Columns

CIM Trap SO3 Column: Pre-purification of USP samples and capture of AAV capsids
The CIM Trap column is a critical component of the PATfix AAV Switcher Platform, utilizing CEX chromatography to capture AAV capsids and facilitate subsequent AEX analysis of USP samples. This seamlessly optimized approach enables the shortening of the time to result without compromising the quality of the separation.

Key Features:
- **Technology:** Employs cation exchange chromatography, leveraging ionic interactions to separate AAV capsids from negatively charged impurities.
- **Application:** Designed for pre-purification of USP samples. The main elution fraction from this CEX method contains concentrated and pre-purified AAV capsids, which are further introduced to AEX AAV analysis.
- **Functionality:** Enables efficient impurity reduction, ensuring robust characterization of the subsequent AEX AAV analysis.

CIMac QA HR Column: USP Monitoring and Development
The CIMac QA HR utilizes advanced reproducibility in chromatography techniques, enabling efficient and reproducible separation and estimation of full AAV capsids in USP samples.

Key Features:
- **Technology:** Employs high-resolution chromatography to achieve detailed separation and analysis of AAV capsids.
- **Application:** Specifically designed for the monitoring of USP, ensuring the efficient separation and reliable estimation of AAV capsids.
- **Functionality:** Provides estimation of the percentage of full capsids at various stages of USP, supporting robust process monitoring and its further development.

PATfix System Hardware

Setting up the appropriate hardware for effective and consistent analytical separation of large biomolecules in the AAV USP is a complex process. Crude AAV mixtures comprise the target AAV entity, along with process-related impurities (like genomic DNA, residual pDNA, hcDNA, HCP) and product-related impurities (like partially filled, deaminated, glycosylated or aggregated AAV capsids), most of them having similar biophysical characteristics that make them challenging to detect precisely.

The PATfix AAV Switcher 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.

Prep Autosampler
The autosampler accommodates 10 mL vials. An automated needle wash ensures minimal carryover, while temperature control of the sample tray secures sample stability while waiting for analysis.

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.

MALS Detector
Suitable for particle characterization like AAV particles, including aggregates and complexes. It effectively identifies AAV capsids in complex samples, distinguishing them from other large and/or more concentrated species based on the retention time (these species can be DNA- and protein-related impurities). Therefore, the MALS signal can be used to calculate the percentage of full AAV capsids with greater accuracy.

Fluorescence Detector (Optional)
A fluorescence detector is not the primary detector for determining AAV capsids in USP samples because the complexity of these samples leads to significant interference from protein impurities. However, for purer USP samples, a FLD can be used to estimate the percentage of full AAV capsids. Since there is no significant difference in fluorescence (intrinsic tryptophan) response between empty and full capsids, no correction factor is necessary in this case. Additionally, FLD allows for highly sensitive detection, requiring smaller sample volumes for analysis and resulting in a lower limit of detection (LOD).

Valve Drive With 6-port 2-position Valve
The valve drive is essential to the PATfix AAV Switcher system, as it connects the CEX and AEX columns. It facilitates the merging or separation of flow between the CIM Trap SO3 and CIM QA HR columns, which is necessary for determining full AAV content. To unify flows from CEX to the AEX column, a T-piece connector is additionally used.

PATfix AAV Switcher Platform Applications

Determining the Percentage of Full AAVs During USP

The PATfix AAV8 Switcher method is applicable for AAV capsid profiling, with the key parameter being the determination of the percentage of full AAV capsids in USP samples. This information serves as an effective and reliable tool for upstream process development and monitoring, with the primary goal of maximizing the yield and quality of the viral vectors produced.

Challenges Addressed:
- Estimating full AAV capsids directly from lysed harvest samples.
- Efficiently separating heterogeneous capsid populations.

Solution:
The method's robustness allows for reliable %F determination in USP samples.

Figure 1: *An example of PATfix AAV Switcher Platform comparative analysis for the AAV8 harvest and purified sample. Red – UV 260 nm, Blue – UV 280 nm, Orange – Tryptophan fluorescence, and Black – light scattering (90° angle). Both samples originate from the same batch.*

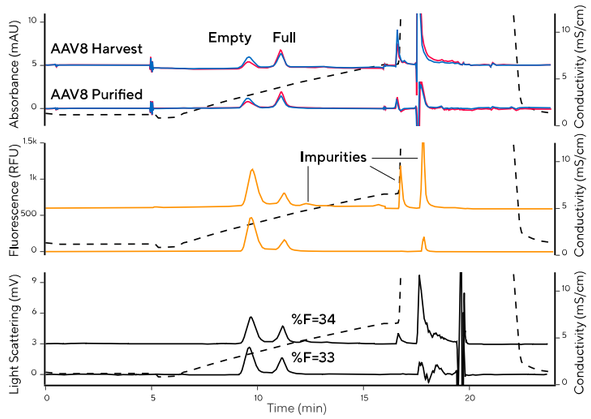


Figure 1 displays an example chromatogram for the analysis of both the AAV8 harvest and purified sample, originating from the same batch, using the PATfix AAV Switcher Platform. This approach does not require pure samples, as it yields consistent results for USP samples.

The method enables enhanced separation between empty and full capsids, allowing for a more reliable determination of full AAV8 capsids. Figure 1 also demonstrates a comparable determination of %F in lysed harvest and purified AAV8 samples, confirming that purified samples are not necessary; instead, initial USP samples can be used. For percentage full AAV calculation, MALS height is preferred, as it provides more accurate results compared to the MALS area signal.

In practice, information regarding the percentage of full AAV8 capsids in USP samples helps us benchmark raw materials, scale up USP processes, and determine optimal kinetics and harvesting points. The optimal harvesting time, identified as 48 hours post-transfection for this exemple USP setup, is summarized in Table 1.

Table 1: *Percentage (%) of full AAV8 as a parameter in the determination of the optimal harvesting point. Hpt – hours post-transfection.*

AAV8 USP Sample hpt [h]	% full (MALS height)
6	NA
18	21.5
24	23.2
30	26.7
42	30.7
48	32.8
54	31.8
72	31.0

Intermediate AAV Species Determination

The PATfix AAV8 Switcher method is a reliable and effective tool for detecting multiple AAV capsid subpopulations that are often overlooked by other complementary techniques.

Challenges Addressed:
Efficient detection and separation of capsid populations with small differences, such as intermediate or partially charged AAV capsids.

Solution:
This technique is an effective and reliable tool for detecting subtle AAV capsid subpopulations.

Figure 2: An example of a chromatogram for the AAV8 purified sample PATfix AAV Switcher Platform analysis. Red – UV 260 nm, Blue – UV 280 nm, and Black – light scattering (90° angle), Black dashed – conductivity.

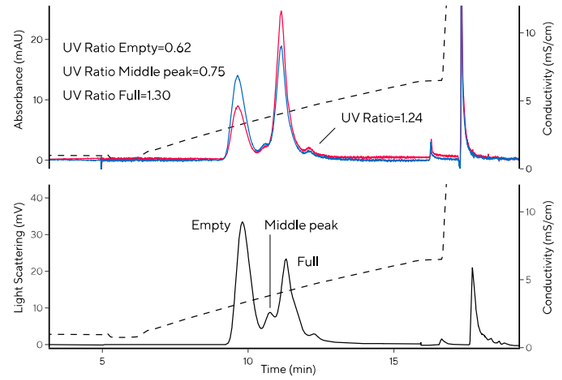


Figure 2 illustrates an example of an AAV Switcher chromatogram for AAV8 purified sample.

In addition to improved baseline separation between empty and full capsids, this method also enables the detailed separation of additional AAV capsids, such as those eluting between empty and full capsids, or capsids eluting after full AAV. These populations are clearly distinguished by differences in UV ratios, as shown in Figure 2.

Qualitative USP Monitoring

The PATfix AAV8 Switcher method can also be used for qualitative monitoring of USP samples. A lower impurity burden in USP samples is preferred during the subsequent steps of AAV production, specifically to simplify downstream processing (DSP). Figure 3 illustrates the AAV Switcher analysis of two AAV8 harvest samples, which differ in transfection reagent and feed/no-feed conditions.

Challenges Addressed:
Controlling high impurity levels in the USP during AAV production using different variables (e.g., transfection reagents).

Solution:
Comparative analysis of USP samples, emphasizing the impurity burden.

Figure 3: *Light scattering (90° angle) profile overlay of the two AAV8 harvest samples. Black – transfection reagent 1; feed; Pink – transfection reagent 2; no-feed. Blank was not subtracted (dashed pink line); Conductivity – dashed black line.*

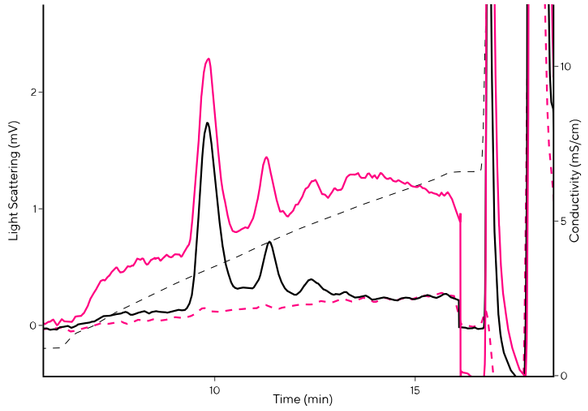


Figure 3 clearly illustrates a higher impurity background when using transfection reagent 2 under no-feed conditions, compared to the stable baseline observed with transfection reagent 1 and feed conditions. In practice, this increased impurity burden (represented by the pink chromatogram) would complicate the subsequent DSP steps.

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	Front panel, Mobile Control, software, event control, analog, terminal protocol
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	Mobile Control (optional)
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

CEX & AEX Pump (2 pcs)

Solvent conveyance	
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
System protection	Soft start, programmable P_{max}
Gradient range	0-100 %
Maximum delivery pressure	400 bar
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: hydrochloric acid and halogenated hydrocarbons, in particular hexafluoroisopropanol (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 chamber	Polypropylene and stainless steel
Vacuum pump	Low hysteresis

Communication	
Interfaces	LAN
Control	LAN
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	See "Device Variants” below
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 formation	
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

Valve Unifier

Valve drive	
Function	Column selection, Eluent selection, Fraction collection, Injection, Sample selection, Bypass, Reverse flow
Port number	Depending on valve
Position	2-position and multi-position valves supported (max. 16 pos.)

Communication	
Interfaces	LAN, display, terminal strip
Control	Display, software, event control
Inputs	Binary control: Home, Backward | Inject, Forward | Load, Start IN
Outputs	Trigger out, Event

General	
Power supply	External DC 24V, 65 W
Dimensions (W × H × D)	80 × 123 × 192 mm
Weight	1.9 kg
Ambient conditions	Temperature range: 4–40 °C; 39.2–104 °F, below 90 % humidity (non-condensing)

6-port 2-position valve	
Function	Fraction collection, Eluent selection, Sample selection
Capillary connection	1/16"
Bore size	0.75 mm
Thread	10-32 UNF
Max. pressure [bar]	240 BAR
Max. pressure [MPa]	24 MPa
Max. pressure [psi]	3480 psi
Port number	6
Positions	2 positions
Stator material	PEEK
Rotor material	PEEK
Material	Biocompatible
Operated	electrical by valve drive

General	
Dimensions	Valve diameter: 42 mm
Weight	0.2 kg
Ambient conditions	Temperature range: 4–40 °C; 39.2–104 °F; below 90 % humidity (non-condensing)

Autosampler

Sample injection	
Max. plate | vial height	47 mm (incl. septa or capmat)
Sample capacity	30 × 10 mL prep autosampler vials
Injection volume range	50 – 8000 µL recommended
Sample loop	10000 µL
Dispenser syringe	2500 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
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	Partial loop filling
Injection precision	RSD (Relative Standard Deviation): Partial loop filling at injection volumes > 50 µL: < 0.5 %
Sample carryover	<0.1 % with needle cleaning
Injections per vial	Max. 9 injections
Injection cycle time	Min. 7 s from the same vial, 14 s from different vials; <60 s for >100 µL sample injection in all injection modes, incl. 300 µL needle wash
Analysis time	Max. 9 h, 59 min, 59 s

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)	377 × 300 × 5755 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 ×129 × 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

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	10^3 to 10^9 Da depending on sample
Radius of gyration range	Approx. 8 nm to 250 nm depending on sample
Laser specifications	532 nm (green) 2.5 – 50 mW adjustable Other wavelength and filter options available on request
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 × 26 cm × 16 cm
Shipping weight	17 kg

Optional Fraction Collector

Fraction collection	
Fractionation modes	Drop counting, time intervals, volume intervals, level
Max. flow rate	25 mL/min or 125 mL/min
Fraction capacity	Depends on rack type
Diverter valve	Drop former (NC): 110 µL waste (NO): 130 µL
Wetted materials	Valve: PEEK and perfluoroelastomer (FFKM) Supplied ferrules: ETFE Supplied valve tubing: PTFE Supplied drain tubing: vinyl
Fractionation control	Operator: direct communication via Ethernet (TCP/IP)
Maximum test tube height	160 mm
RFID rack recognition	No
Number of racks	1
Capillary connection	1/16" or 1/8"

Communication	
Control	LAN

Technical parameters	
Conformity	CE, CSA
Display	Touch screen LCD displays
Ambient conditions	0–40 °C, 32–104 °F

General	
Power supply	100–240 VAC, 50–60 Hz, max. 1 A
Dimensions (W × H × D)	311 × 330 × 355 mm
Weight	7.1 kg

Rack type	**Fraction capacity**
15 mL centrifuge tubes	72
1.5 mL microcentrifuge tubes	60
50 mL centrifuge tubes	36
24 & 96-well plates	2

Software

Software name	PATfix®
Version	3.0.25006.783
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 Column thermostat CT 2.1 Valve unifier VU 4.1 Monitor CM 2.1S/pH 2.1S Fraction collector foxy R1 Monitor mikron 81
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 Switcher Platform

AAV8 Switcher Method

Column chemistry	SO3, QA
Attribute	Direct full AAV content in complex USP samples
LOQ	4.61×10^9 vg/mL

System Requirements

Computer & Operating System

Architecture	**Minimum requirements**
Operating system	Windows 11 | 10 | 8.1 | 7
CPU	Minimum 1 CPU core @ 2 GHz speed, multi-core CPU recommended
RAM	Minimum 4 GB, recommended 8 GB
Graphics	Onboard (integrated) graphics
Free disk space	256 GB for installation and data storage The program uses approx. 1 GB of disk space The chromatogram file size ranges between 2 and 5 MB SSD instead of HDD is highly recommended
Interfaces and PC slots	LAN connection
Monitor	Minimum 1680 × 768, recommended 1920 x 1080

Bench Space and Socket Requirements

PATfix® AAV Switcher	
Lab footprint (W × H × D)	250 cm × 70 cm × 100 cm
Number of electrical sockets	13

Fluorescence detector	
Additional lab footprint (W × H × D)	30 cm × 70 cm × 40 cm
Number of additional electrical sockets	1

Fraction collector	
Additional lab footprint (W × H × D)	40 cm × 70 cm × 50 cm
Number of additional electrical sockets	1

All-in-one PC and Monitor	
Additional lab footprint (W × H × D)	40 cm × 70 cm × 60 cm
Number of additional electrical sockets	1

Maximum Power Draw Requirements

PATfix AAV Switcher

Device	**Max. power consumption (W)**
UV-Vis detector	65
MALS detector	155
Pump	2 x 100
Conductivity monitor	60
Autosampler	200
Column thermostat	100
Valve unifier	65
Other	65
Total	**910**

Optional Components

Device	**Max. power consumption (W)**
Computer	90
Fraction collector	240
FLD detector	400

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