



# **OMNISEC**

Unlock the power of advanced separations



# **Multi-detection SEC** for you

Multi-detection Size Exclusion Chromatography (SEC) or Gel Permeation Chromatography (GPC) is an essential analytical technique for the characterization of macromolecules. It provides deep insights into your sample's absolute molecular weight, composition, size and structure.

A series of three different detectors delivers critical information about your sample:

Light scattering measures absolute molecular weight, independent of column retention volume or standards

2

**Differential viscometry** 

measures the intrinsic viscosity of a sample to determine size and structure

**Refractive Index and UV-PDA** detection measure the sample's concentration and composition.



Malvern Panalytical's OMNISEC system was a powerful tool to confirm the identity of peaks by determination of the molecular weight of monomer, dimer and trimer species of a novel fusion protein.

This could not be achieved unambiguously using SEC with conventional UV.

> Patrick Merky Senior Scientist Cobra Biologics



### **Bioscience and biopharmaceuticals**

- Quantify key metrics in stab profiling and biosimilarity
- Streamline protein conjugat protein-protein, protein-pol glycoprotein, drug antibody
- Accurately measure monom fragments and higher order

### **Polymers, plastics, fibers and elastomers**

- Maintain product quality by understanding the effects o raw material supply, synthes or manufacturing processes
- Gain insight into degradatio products, additives or impu

### Academia

- SEC/GPC is an essential tec for a wide range of research themes, including polymers biopolymers and proteins
- Establish the success of pol or polymer degradation

### Paints, inks and coatings

• The efficacy of printed polyr is linked to their macromole properties, including molecu weight distribution and strue

### **Foods and drinks**

- Control the depolymerization native polysaccharides to pr specific thickening propertie
- Monitor the degradation of polysaccharides due to processing or blending of different source materials

### **Pharmaceuticals and drug delivery**

 Polymeric excipient properti relate directly to a drug prod safety, quality and clinical ef

bility		aggregates, independent of
		column retention volume, for
tion analysis-		protein, virus and VLP samples
ymers,	•	Directly measure AAV titer and
ratios (DAR)		percentage filled, as a replacement
ner,		for qPCR and ELISA-based assays

of changing sis s on rities	<ul> <li>Safeguard the performance of the final product by understanding the impact of conventional or advanced processing technologies on critical material properties</li> </ul>
chnique h s,	<ul> <li>Identify biocompatible and biodegradable polymers which can be used as substitutes for synthetic polymers</li> </ul>
lymerization	<ul> <li>Characterize currently unknown proteins or establish the properties and purity of samples</li> </ul>

•	Understand the link between printing and the degradation of polymers
	•

on of	<ul> <li>Molecular properties (MW, IV) relate</li> </ul>
roduce	directly to the bulk properties of
es	food ingredients, impacting their
	mouthfeel and performance

es
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ficacy

- Understand the clearance rates of topical solutions such as eye drops by measuring product viscosity
- Link the release rates of therapeutics to the structure of the drug carrier

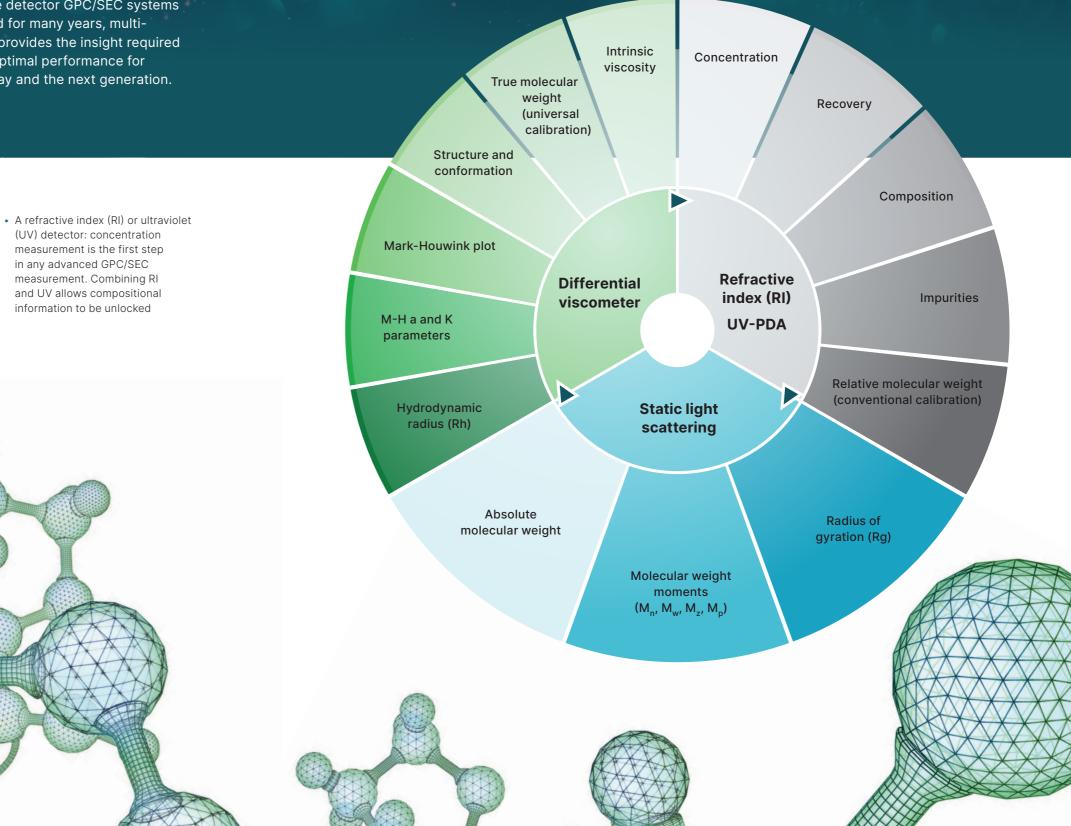
# Why use multi-detection SEC?

A modern research environment demands a complete understanding of a sample's molecular properties, including accurate and reliable measurements of molecular weight. SEC is a well-established technique which separates the molecules in a sample according to their hydrodynamic volume as they enter and exit the pores of a porous gel matrix packed inside a chromatography column.

Like other HPLC-based techniques, this involves the use of a pump, a column and at least one detector to measure the sample as it elutes. Although single detector GPC/SEC systems have been used for many years, multidetection SEC provides the insight required to deliver the optimal performance for samples of today and the next generation.

# **OMNISEC** multi-detector system

The ultimate in advanced detection is the combination of all these detectors to get a complete understanding of the molecule being investigated



- A light scattering detector: the heart A viscometer: probes the very of an advanced GPC/SEC system. Light scattering enables absolute molecular weight calculation, independent of structure and sample retention volume
  - structure of a molecule to give a sample's intrinsic viscosity. No other detector can match its sensitivity to structural changes
- (UV) detector: concentration measurement is the first step in any advanced GPC/SEC measurement. Combining RI and UV allows compositional information to be unlocked

# A new standard in GPC/SEC

Our complete and integrated gel permeation / size exclusion chromatography solution comprises:

### OMNISEC RESOLVE

an integrated pump, degasser, autosampler and column oven for managing the separation within a single advanced unit

### OMNISEC REVEAL

an integrated multi-detector module

**OMNISEC software** - for easy and intuitive sample analysis

**SEC-MALS 20** - for additional light scattering insights.



### Quicker, simpler, safer

- Autosampler temperature control (4°C 60°C) protects proteins from degradation and improves polymer dissolution
- Waste-free injections from vials or 96 well micro-titer plates mean less volume of precious samples is required
- Low volume degasser enables faster mobile phase exchanges for increased system productivity
- Inert (316 stainless steel) viscometer pressure transducers for wide pH range use
- System temperature control (up to 65°C) reduces operating backpressure
- Revolutionary user-exchangeable viscometer capillary module reduces service time and costs

### **Gives better results**

- The new, incredibly sensitive light scattering detector enables measurements of molecular weights as low as 200 g/mol, injection masses as low as 100 ng of material, and samples with low dn/dc
- Integrated detector module minimizes
   inter-detector band broadening
- Column and detector temperature control (20°C - 65°C) improves resolution and baseline stability
- Flexible autosampler delivers accurate and precise volumes for unparalleled data reproducibility

# **OMNISEC** software

### Powerful by design, yet easy and intuitive to use

### Workflow-focused software

OMNISEC software has been designed with your priorities in mind to make GPC/SEC analysis easy and intuitive. The software guides you smoothly through setup, data acquisition and analysis in an intuitive workflow.

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Char Selection Provide database	Sample sep	uence name Protein Molecular Weight Standards	& tpd									
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- Fully automated system setup, acquisition and shut down, so running your samples is as simple as inserting your vials or plates and pressing 'Start'
- Just one click takes you from raw data to results
- With fully-customizable reporting features, you can clearly see the data that's most important to you
- Optional 21 CFR Part 11 compliant security package, to ensure peace of mind for those working in regulated environments
- State-of-the-art band broadening corrections
- Conventional and Universal calibration enabling the use of traditional column retention volume methods.



Can be used as the preferred method of analysis or to help in method transfer to light scattering techniques

- Compositional analysis of conjugates and copolymers to measure the concentration and associated material parameters of two components within a sample
- Particle titer and Percentage full measurements for drug delivery vectors, including Adeno-associated virus (AAVs)
- Widely used for the measurement of Drug:antibody ratios (DARs)

# **OMNISEC REVEAL overview**

### Integrated multi-detector module

OMNISEC REVEAL is an integrated multi-detector module for advanced GPC/SEC measurements, incorporating refractive index, UV/Vis absorbance, light scattering and intrinsic viscosity detectors. The high sensitivity and measurement quality provided by OMNISEC REVEAL ensures maximum return on your investment.

OMNISEC REVEAL can act as a standalone detector connected to your existing GPC/SEC system, or can work in combination with the OMNISEC RESOLVE module to provide a complete GPC/SEC solution.

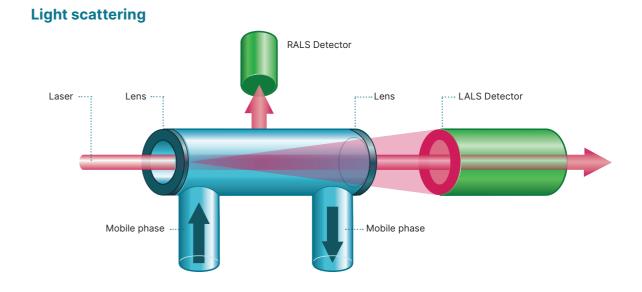
Its integrated design keeps all the detectors in one compartment, affording multiple advantages:

- Inter-detector tubing is minimized, reducing band broadening to improve data quality and result accuracy
- The detectors and the inter-detector tubing are all maintained at the same temperature to further improve data quality by maintaining baseline stability



# **OMNISEC REVEAL detectors**

### **Detector modules**



The unique light scattering detector combines the sensitivity of 90° Right Angle Light Scattering (RALS) with the accuracy of 7° Low-Angle Light Scattering (LALS). This makes it the ideal choice for measuring precious samples where only small injections can be afforded, or samples with low dn/dc, while its 18  $\mu$ L flow cell maintains sample resolution.

### **OMNISEC REVEAL key features and benefits**

# Market-leading light scattering detection

- Measure low molecular weight samples with greater accuracy (down to 200 g/mol)
- Work at lower sample concentrations (newly synthesized polymers and proteins) with no impact to data quality
- Measure low dn/dc samples with unsurpassed accuracy and sensitivity
- High sensitivity Refractive index
- Greater accuracy and less subjectivity at lower concentrations

### Measure lower concentrations of highly viscous materials to prevent column overload

# Self-Balancing Viscometer detector

- Improved data quality and accuracy
- Integrated robust
   differential viscometer
- Measure Intrinsic Viscosity (IV) of samples to determine structure and conformation
- Robust to all GPC solvents and a wide pH range, broadening available applications

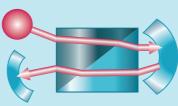
## Fully-integrated detector module

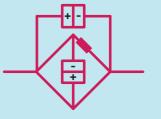
- Excellent temperature control and reduced inter-detector volume results in the highest-quality data
- Improved separation quality and resolution
- Unrivalled baseline stability on all detectors for greater sensitivity to low sample concentrations

### All detectors in series

 Detectors are placed in series rather than in parallel. This avoids splitting the sample and risking data quality

### **Refractive index**

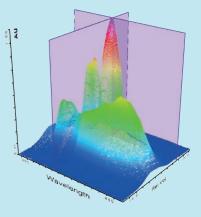




OMNISEC REVEAL's refractive index detector measures the concentration of almost any solute. Its robust flow cell allows it to be run in series with other detectors, maximizing sensitivity and minimizing band broadening. The new pressure transducers in OMNISEC REVEAL's differential viscometer improve baseline stability, sensitivity and robustness. Their 316 stainless steel construction ensures solvent and pH compatibility. It has an interchangeable capillary module for fast user replacement and the ability to self-balance for simple, automatic setup.

### Intrinsic viscosity

### UV/Vis



The UV/Vis photodiode array (PDA) covers wavelengths of 190 nm - 900 nm, opening up absorbance measurements to a wider application range.

# **OMNISEC RESOLVE overview**

OMNISEC RESOLVE is a combined pump, degasser, autosampler and column oven for mobile phase delivery and sample injection.

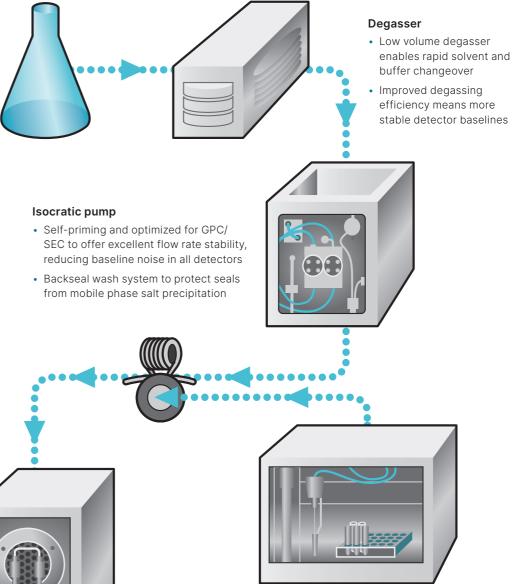
What benefits does the complete OMNISEC GPC/SEC system provide?

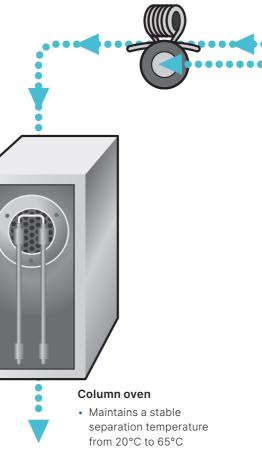
- One solution from a single manufacturer with an intuitive software package that handles everything from instrument control to data acquisition and data analysis
- Unattended operation using the autosampler, even with sensitive samples such as proteins, thanks to its temperature control

### **OMNISEC RESOLVE key** features and benefits

- Low pulsation pump provides unparalleled baseline stability
- Low volume degasser reduces downtime with rapid solvent changeover and equilibration
- Temperature-controlled autosampler (4°C to 60°C) protects fragile samples from degradation and reduces the viscosity of samples in high viscosity samples such as DMSO
- Zero overhead autosampler minimizes the waste of precious samples
- Integrated column oven ensures high-quality separations and component resolution







• Accommodates up to 6 analytical columns or 2 GE Tricorn<sup>™</sup> columns

### Autosampler

- Zero injection volume overhead mode prevents sample wastage
- · Injects samples from vials or 96well microtiter plates with unrivalled accuracy and precision
- Maintains sensitive samples such as proteins at 4°C to protect them from aggregation
- Warms viscous samples such as those in DMSO to 60°C to improve injection volume accuracy

# **SEC-MALS 20 detector**

### Molecular size and absolute molecular weight

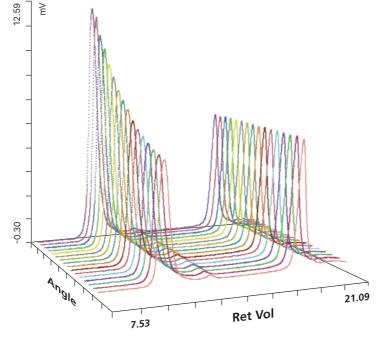
The SEC -MALS 20 is a modular multiangle light scattering (MALS) detector for the OMNISEC system. It serves as a powerful additional detector which complements RALS/LALS or can be used as the sole light scattering detector.

The SEC-MALS 20 is also flexible enough to easily be combined with any existing GPC/SEC system, for direct measurements of absolute molecular weight and size.



The key to the performance of the SEC-MALS 20 detector is its vertical flow cell with radial optics. This ensures:

- Reduced detector noise at low angles
- Reduced need for detector cleaning
- Fixed, constant and known measurement angles, regardless of solvent type
- One cell for all solvents, so no need to switch or remove the cell between assays
- Reduced band broadening and tailing compared with other MALS detectors, thanks to its low volume



MALS signals from an aggregated protein and monomer

# SEC-MALS 20 detector specifications

Parameter	Specification
Laser type	Diode
Laser wavelength	660 nm
Laser power	120 mW max, 100 mW to cell
Laser lifetime	>10,000 hours
Number of scattering angles	20 or 9
Scattering angle positions	12°, 20°, 28°, 36°, 44°, 52°, 60°, 68°, 76°, 84°, 90°, 100°, 108°, 116°, 124 132°, 140°, 148°, 156°, 164°
Cell volume	63 µL
Scattering volume	<7.8 nL
Analog signals accepted	4 x ±10 V 24 bit
Data acquisition rate	5 Hz
Molecular weight range	<1000 up to more than 10 <sup>7</sup> g/mol*
Molecular weight accuracy	±2% for NIST standard SRM 1478
Radius of gyration range	10 nm - 150 nm* using SEC <sup>+</sup>
Limit of quantification	1 μg Polystyrene 105 kDa, 2 μg BSA <sup>††</sup>
Analysis models	Zimm, Berry, Debye
Fit order	1 <sup>st</sup> to 5 <sup>th</sup>
Detector range	4000 mV at 24 bit
Linear range	4000 mV at 24 bit
Baseline noise	<0.05 mV at 90°
Baseline drift	<0.05 mV/hour at 90°
Temperature range	10°C above ambient up to 60°C
Voltage	90-250 V, 50/60 Hz
Power usage	60 W
Dimensions	16 cm x 26 cm x 46 cm (h, w, d)
Weight	16.5 kg
21 CFR Part 11	OMNISEC software compliant

\* Sample dependent

† 10 nm - 500 nm when used FFF separations

tt Chromatography dependent. Data collected under standard SEC conditions (two x 8 mm x 300 mm SEC columns)

# **Product specifications at a glance**

OMNISEC System				
Parameter	Specification			
Parameters measured	Molecular weight (Mn, Mw, Mz), dispersity (Mw/Mn), Hydrodynamic radius (viscosity), Radius of gyration, Intrinsic viscosity, Mark-Houwink a & K, Weight fraction, Concentration (per peak, total and composition), dn/dc, dA/dc, Sample composition, Titer, % full AAV, DAR			
Recommended computer specification	Windows ® 10 64bit OS, 4th generation i7 processor, 8GB physical memory and 1TB hard drive & DVD drive			
Data collection rate	100 Hz			
Patents	US 14/599,033, US20140060162A1 & EP2619543B1, US20140144214A1 & EP2619544A1			

### OMNISEC RESOLVE

OMINISEC RESOLV	ļĒ ,						
	Parameter	Specification					
	Dimensions (w, d, h)	42 cm x 64 cm x 89 cm (w, d, h)					
	Weight	62 kg					
	Power requirements	600 W					
	Principle	Isocratic pump with continuous backseal washing					
	Flow rate range	0.05 mL/min - 10 mL/min					
Pump	Flow rate accuracy	±1% mL/min					
	Pressure range	0 - 5000 PSI (34.5 MPa)					
	Pulsation	0.1456% @ 1 mL/min in water					
Democra	Degassing capacity	>90%					
Degasser	Volume	960 µL					
	Number of samples	Up to 192					
	Sample container types	HPLC vials; 96-well microtiter plates					
	Temperature control range	4°C - 60°C					
	Injection volume range	1 μL - 300 μL					
Autosampler	Injection volume accuracy	>99.5%					
	Injection volume precision	<0.3% RSD in full loop mode <0.5% RSD in partial loop mode <1% RSD in µL pickup mode					
	Injection overhead volume	0 μL in μL pickup mode					
	Syringe volume	250 μL standard					
Column oven	Column capacity	6 x analytical columns (2 x Tricorn 10/300 GL)					
Column oven	Temperature control range	20°C - 65°C					

	Parameter	Specification				
	Dimensions (w, d, h)	42 cm x 64 cm x 60 cm (w, d, h)				
	Weight	40 kg				
	Power requirements	600 W				
	Detector temperature control range	20°C - 65°C				
	Dynamic range	±2.5 ×10 <sup>-4</sup> RIU				
	Baseline noise	<10 <sup>-7</sup> RIU				
Differential	Baseline drift	<3×10 <sup>-7</sup> RIU/hr				
refractive index detector	Minimum quantifiable mass	100 ng of 100 kDa molecular weight polystyrene in THF* 100ng of BSA in PBS*				
	Flow cell volume	12 µL				
	Wavelength	640 nm				
	Baseline noise	2×10 <sup>-5</sup> AU				
	Baseline drift	5×10 <sup>-4</sup> AU/hr				
	Wavelength range	190 nm - 900 nm				
Diode-array- based UV/Vis	Wavelength accuracy	<1 nm				
spectrometer	Wavelength resolution	0.6 nm				
	Number of wavelengths	1024				
	Flow cell volume	7.5 µL				
	Path length	10 mm				
	Principle	RALS/LALS				
	Operating angles	90° & 7°				
	Dynamic range	2500 mV				
	Baseline noise	<0.1 mV				
light coattoring	Baseline drift	<0.2 mV/hr				
Light scattering detector	Minimum quantifiable mass	100 ng of 100 kDa molecular weight polystyrene in THF* 100ng of BSA in PBS*				
	Molecular weight range	200 g/mol to more than 10 <sup>7</sup> g/mol				
	Flow cell volume	18 µL				
	Laser	50 mW				
	Laser wavelength	640 nm				
	Principle	4-capillary Wheatstone bridge with self-balancing mechanism and user-exchangeable capillaries				
	Differential pressure dynamic range	±2500 Pa				
	Differential pressure baseline noise	0.3 Pa				
1-capillary	Inlet pressure dynamic range	100 kPa				
4-capillary differential	Inlet pressure baseline noise	0.01 kPa				
viscometer	Baseline drift	<0.2 kPa				
	Minimum quantifiable mass	1 μg of 100 kDa molecular weight polystyrene in THF*				
	Detector volume	17 μL/capillary				
	"Delay reservoir" volume	8 mL per column				
	Protection	Firmware-based transducer overpressure protection				

\*Data collected under standard SEC/GPC conditions (two x 8 mm x 300 mm SEC/GPC columns)



# Why choose us?

# When you make the invisible visible, the impossible is possible.

Our analytical systems and services help our customers to create a better world. Through chemical, physical and structural analysis of materials, they improve everything from the energies that power us and the materials we build with, to the medicines that cure us and the foods we enjoy.

We partner with many of the world's biggest companies, universities and research organizations. They value us not only for the power of our solutions, but also for the depth of our expertise, collaboration and integrity.

With over 2200 employees, we serve the world, and we are part of Spectris plc, the worldleading precision measurements group.

### Malvern Panalytical. We're BIG on small™

# **Service & Support**

Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment with us, and ensure that as your laboratory and analytical needs grow, we are there to support you.

Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response and maximum instrument uptime.

- Local and remote support
- Full and flexible range of support agreements
- Compliance and validation support
- Onsite or classroom-based training courses
- e-Learning training courses and web seminars
- Sample and application consultancy





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