C190-E292B

SHIMADZU
Excellence in Science

High Performance Liquid Chromatograph

Nexera lite inert

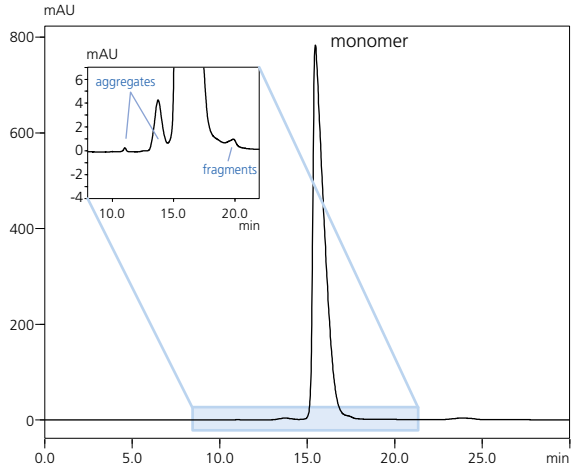
Nexera lite inert

The analysis of proteins such as antibody drugs requires careful operation because a high-salt mobile phase sometimes corrodes the system. In addition, the adsorption of proteins to metal surfaces often results in poor chromatographic performance.

Nexera lite inert is a robust HPLC system that eliminates the risk of corrosion by high-salt mobile phases and sample adsorption onto metal surfaces. It improves the data quality of protein analysis in biological samples with superior reproducibility, without any special considerations for stable and long-term use.

Improved Data Reliability by Preventing System Corrosion from Halogenic Salt

For analysis of antibody drugs or proteins in biological samples, a metal-free LC system is required for good repeatability over a long time due to high-concentration, salt-containing mobile phases such as Sodium chloride. With no metal material in the flow path, Nexera lite inert provides stable aggregate assay results with good repeatability.



Monoclonal IgG antibody aggregate analysis by gel filtration chromatography

Analytical Conditions

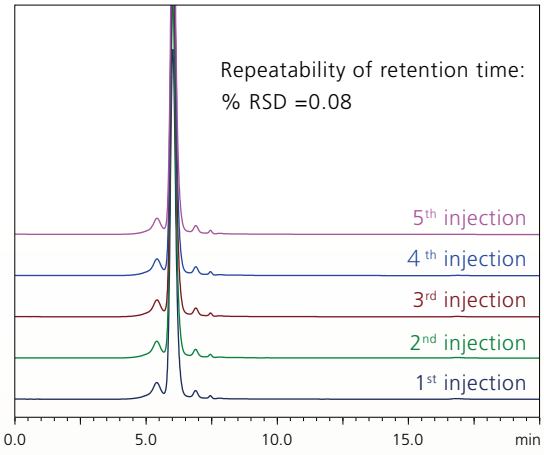
Mobile phase:	0.2 mol/L Potassium phosphate buffer containing 0.25 mol/L Potassium chloride (pH 6.2)
Flow rate:	0.5 mL/min
Column:	TSKgel G3000SWXL (300 mm×7.8 mmI.D., 5 µm)
Column temp.:	Ambient
Detection:	UV, 280 nm

Stainless-steel pump LC-40i

Corrosion resistance test results of pump heads

Superior Retention Time Stability by Highly Accurate Solvent Delivery

With outstanding flow-rate stability, the Nexera lite inert provides excellent retention time repeatability.



Analysis of the aggregates in the antibody drug (n=5)

Analytical Conditions

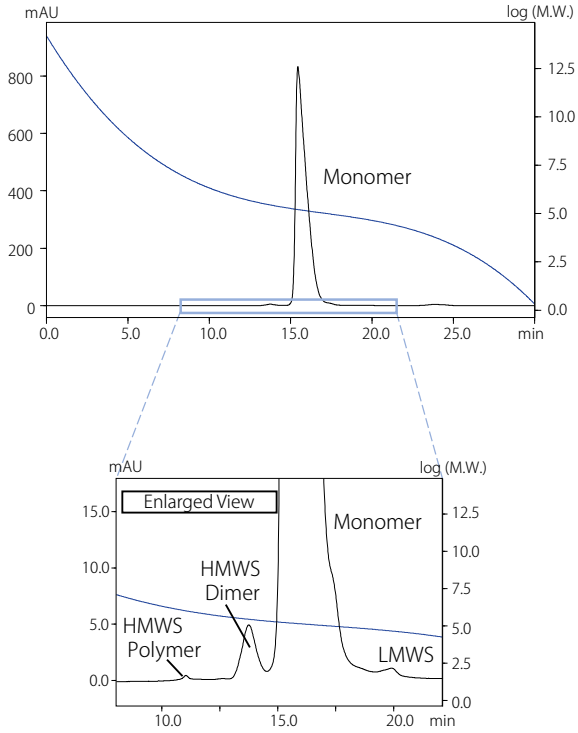
Mobile phase:	0.1 mol/L Potassium phosphate buffer (pH 7.0) containing 0.2 mol/LSodium chloride aq.
Flow Rate:	0.5 mL/min
Column:	Shim-pack Bio Diol (300 mm×4.6 mm I.D., 5 µm)
Column temp.:	25℃
Detection:	UV, 280 nm

Real-Time Monitoring of Mobile Phase pH

In ion exchange or gel filtration chromatography, the pH of the mobile phase sometimes affects the separation of compounds. The pH Monitor, pHM-40, continuously monitors and records the pH of the mobile phase. The pH and detector chromatograms are saved within the same data file and can be overlapped, ensuring efficient data traceability.

Analysis of Antibody Drugs by Gel Filtration Chromatography

Antibody aggregates indicate the immunogenic potential. In addition, aggregates can result in lower purification efficiency and lower production quantities of antibodies, which are the main active ingredient in antibody drugs. Therefore, antibody drug aggregate analysis is an important process in the manufacturing and quality control of biopharmaceuticals. Using a Nexera lite inert system ensures reliable data can be acquired without worrying about protein adsorption or the risk of corrosion by high salt concentrations.

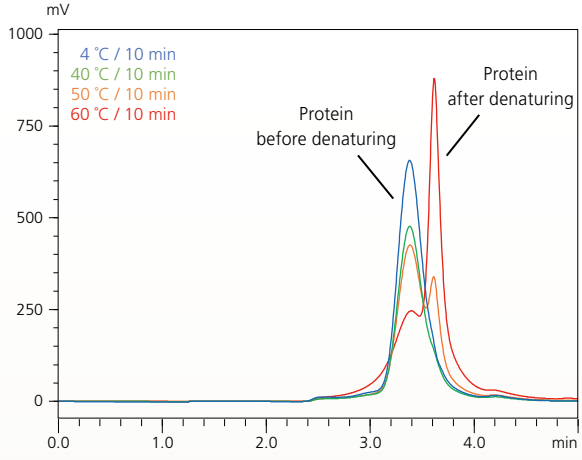


Chromatogram (black) and Calibration Curve (blue) from USP Reference Standard IgG Monoclonal Antibody Solution (10 mg/mL)

Analysis of Structural Changes in Proteins Using a Fluorescence Detector

In addition to a general-purpose absorbance detector, Nexera lite inert systems support using a metal-free inert cell with a fluorescence detector, expanding their use to a wider range of applications.

The figure on the right is from an example of using gel filtration chromatography to evaluate the molecular weight distribution of heat-treated membrane proteins that contain green fluorescent protein (GFP). It shows that structural changes due to the heat treatment temperature can be detected by fluorescence detection.



Chromatogram of Membrane Protein with GFP Before/After Heat Treatment
(Evaluated with Fluorescence Detector)

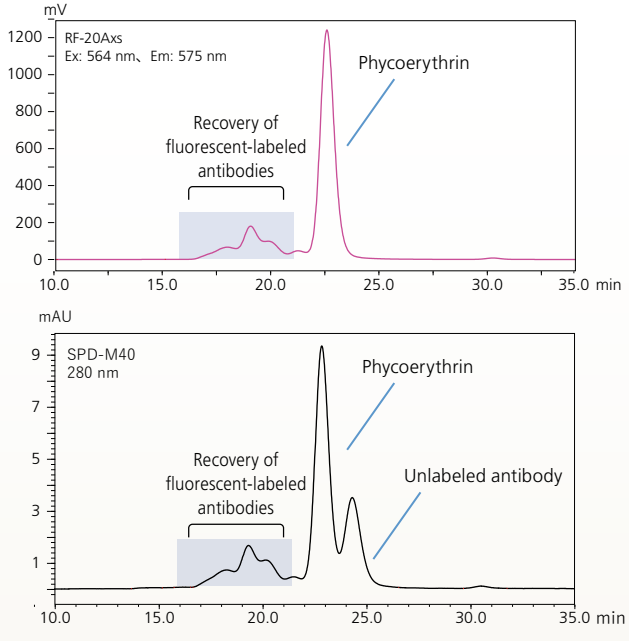
Target Compounds Recovered with a Fraction Collector for the Next Analysis Step

Preparative separation of target peaks is possible by connecting an FRC-10A fraction collector to the Nexera lite inert system. The FRC-10A includes no metal materials in flow channels, which allows the configuration of systems that are fully inert through to target recovery. In addition, the FRC-10A is compatible with 1.5 mL tubes, 15 mL centrifuge tubes, and 96-well DWPs, so targets can be collected in containers appropriate for subsequent process steps.

Nexera lite inert System with FRC-10A Fraction Collector

Purifying and Selectively Recovering Fluorescently Labeled Antibodies

Using a combination of multiple detectors and fraction collectors offers the flexibility to purify samples based on the specific characteristics of target compounds. For example, by using both an absorbance detector and fluorescence detector, antibodies with and without fluorescent labeling can be monitored at the same time. Furthermore, by using an FRC-10A fraction collector to ensure reliable preparative separation of only target components, fluorescently labeled antibodies can be used directly in the next process step.



Chromatogram of Phycoerythrin-Labeled Antibodies
(Upper: Fluorescence Detector; Lower: Absorbance Detector)

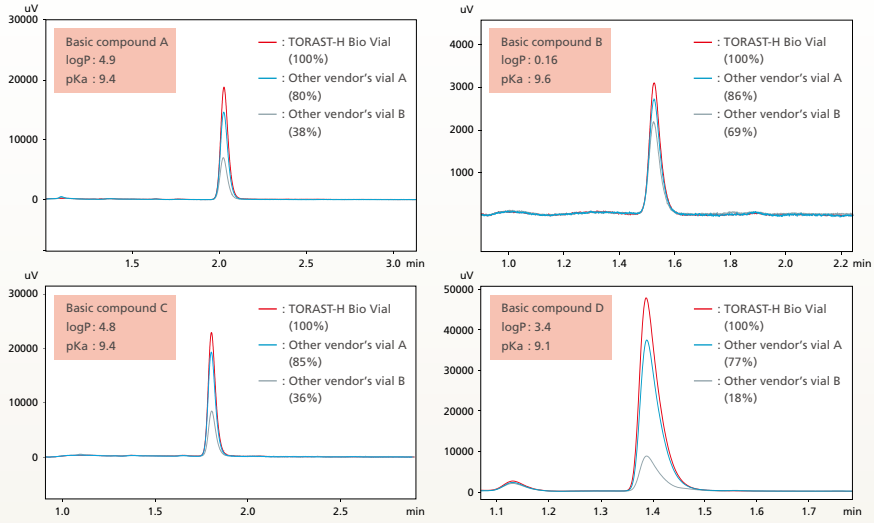
Comprehensive Solution for Increasing Bioseparation Efficiency

Adsorption of biomolecules can occur not only within instruments, but also in vials, columns, and other equipment used during sample preparation. Shimadzu offers support for resolving such issues with products that feature unique technologies for inhibiting adsorption.

State-of-the-Art Technology for Inhibiting Adsorption and Increasing Recovery Rates

TORAST™-H Bio Vial

Compounds are most likely to adsorb to vials they contact the longest. TORAST-H Bio vials offer exceptional resistance to adsorption by biomolecules, which helps maximize recovery rates from valuable samples and increase sensitivity for analyzing trace components.



Selecting Analytical Columns Based on Target Components and Objectives

Shim-pack™ Series Columns

Shimadzu offers columns optimized for a variety of separation modes to analyze biomolecules, such as proteins, peptides and nucleic acids.

Nucleic Acids
Oligonucleotides

- Reversed phase → Shim-pack Scepter™
- Ion exchange → Shim-pack Bio IEX
- Size exclusion → Shim-pack Bio Diol

Proteins
Antibodies,
Antibody Drug Conjugates

- Peptide digests → Shim-pack Arata™, Shim-pack Velox™, Shim-pack GISS
- Aggregates and fragments → Shim-pack Bio Diol
- Charge variants → Shim-pack Bio IEX
- Conjugates → Shim-pack Bio HIC

Specifications

System Controllers


SCL-40


CBM-40

	SCL-40	CBM-40	CBM-40lite
Monitors	Touch panel LabSolutions™ Web monitor	LabSolutions Web monitor	LabSolutions Web monitor
Connectable unit	Solvent delivery unit: Max. 4, Autosampler: 1, Column oven: Max. 4, Detector: Max. 2, etc.		
Number of connectable units	8 (Using option: 12)		4 (Excluding built-in solvent delivery unit)
Event input/output	Input: 1, output: 2		
Analog board	Up to 2 channels (option)	Up to 1 channel (option)	—
Communication	Ethernet		
Reservoir tray	Built-in	—	
Dimensions [mm], weight	W 260 × D 500 × H 140, 6 kg	W 260 × D 500 × H 72, 5 kg	—
Operating temperature range	4 to 35 ˚C		
Power supply	AC 100 to 240 V, 50 VA, 50/60 Hz		Supplied from solvent delivery unit

Solvent Delivery Unit


LC-40i

	LC-40i
Pumping method	Serial-type double plunger
Allowable maximum pressure	Water: 30 MPa (≤ 4.0000 mL/min) Organic solvents: 22MPa (≤ 4.0000 mL/min) Water and Organic Solvents: 15 MPa (4.0001 to 5.0000 mL/min)
Flow rate setting range	0.0001 to 5.0000 mL/min
Flow rate accuracy	±2% or ±2 µL/min Whichever is greater (Specified conditions)
Flow rate precision	≤ 0.06% RSD or 0.02 minSD Whichever is greater
Gradient mode	High-pressure gradient (2 or 3 solvents) Low-pressure gradient (4 solvents)
Gradient range of set concentrations	0 to 100% (0.1% step)
Gradient concentration accuracy	HPGE: ±1.0% (1 mL/min, 10 MPa, water / caffein aq.) LPGE: ±1.0% (1 mL/min, 10 MPa, water / caffein aq.)
Wetted materials	PEEK, ruby, sapphire, Perfluoroelastomer, high molecular weight polyethylene
Available pH range	1 to 14
Automatic rinsing kit	Optional
Degassing unit	1 unit connectable
Dimensions [mm], weight	W 260 × D 500 × H 140 mm, 10 kg
Operating temperature range	4 to 35˚C
Power supply	AC 100V to 240V, 150 VA, 50/60 Hz

Degassing Units


DGU-403

	DGU-403	DGU-405
Number of degassed solvents	3	5
Wetted materials	PEEK, PTFE	
Degassed flow line capacity	400 µL/1 line	
Dimensions [mm], weight	W 260 × D 500 × H 72, 4 kg	
Operating temperature range	4 to 35 ˚C	
Power supply	Supplied from solvent delivery unit	

Autosamplers


SIL-20AC

	SIL-20AC (with inert kit)	SIL-20A (with inert kit)
Injection method	Total-volume injection, Variable injection volume (No sample loss by injection)	
Allowable maximum pressure	Inert kit : 20.0 MPa (Water Solvent) , 14.7 MPa (Organic Solvent) Inert kit with optional expansion 500 µL sample loop : 20.0 MPa (Water Solvent), 9.8 MPa (Organic Solvent)	
Injection volume	0.1 to 50 µL (standard), 0.1 to 500 µL (optional) (0.1 to 0.9 µL : 0.1 µL step, 1 to 500 µL : 1 µL step)	
Injection volume accuracy	≤ ±1% (50 µL injection, n=10)	
Samples for processing	175 (1 mL sample vial), 105 (1.5 mL sample vial), 50 (4mL sample vial) 192 (microtiter plate 96 well × 2 plates), 768 (microtiter plate 384 well × 2 plates)	
Injection volume repeatability	RSD ≤ 0.3% (10 µL injection)	
Carryover	≤ 0.005% (under specified conditions)	
Sample cooler	Standard equipment	—
Sample cooler temperature accuracy	C model : ±3 ˚C (microtiter plate and deep well plate cannot be cooled ≤ ±6 ˚C, 1 ˚C.)	—
Wetted materials	PEEK, PEEK blend, Ceramic	
Available pH range	1 to 14	
Dimensions [mm], weight	W 260 × D 500 × H 415 mm, 27 kg	W 260 × D 509 × H 415 mm, 30 kg
Operating temperature range	4 to 35 ˚C	
Power supply	AC 100 to 240 V, 180 VA, 50/60 Hz	

Column Ovens


CTO-40C CTO-40S

	CTO-40C	CTO-40S
Temperature control type	Forced air circulation	
Cooling method	Electronic cooling	
Temperature control range	Room temperature –10 ˚C to 100 ˚C	Room temperature –10 ˚C to 85 ˚C
Temperature accuracy	± 0.5 ˚C	± 0.8 ˚C
Temperature precision	± 0.05 ˚C	± 0.1 ˚C
Containable column size and number	Up to 250 mm L. column × 6 or 300 mm L. column × 3	Up to 100 mm L. column × 6 or 300 mm L. column × 3
Dimensions [mm], weight	W 260 × D 500 × H 415, 21 kg	W 130 × D 500 × H 553, 15 kg
Operating temperature range	4 to 35°C	
Power supply	AC 100 to 120 V / 220 to 240 V (Automatic switching), 400 VA, 50/60 Hz	AC 100 to 240 V, 300 VA, 50/60 Hz

UV-Vis Detectors


SPD-40V

	SPD-40	SPD-40V
Light source	Deuterium (D_2) lamp	Deuterium (D_2) lamp, tungsten lamp
Wavelength range	190 to 700 nm	190 to 1000 nm
Bandwidth	8 nm	
Wavelength accuracy	≤ ±1 nm	
Wavelength repeatability	≤ ±0.1 nm	
Drift*	≦0.1 × 10^{-3} AU/h (under specified conditions, typically)	
Noise*	≦5.0 × 10^{-6} AU (under specified conditions)	
Linearity*	2.5 AU (under specified conditions, typically)	
Recommended flow cell	Inert cell (tubing I.D.: 0.3 mm, optical path length: 10 mm, cell volume: 12 µL, equipped with temperature control function) Inert cell for low-pressure-resistant columns (tubing I.D.: 0.5 mm, optical path length: 10 mm, cell volume: 12 µL, not equipped with temperature control function)	
Materials of wetted parts	PEEK, PFA, quartz	
Sampling rate	Max. 100 Hz (Single wavelength mode)	
Cell temperature control range	19 to 50 ˚C, 1 ˚C step	
Optional flow cell	UHPLC inert cell (optical path length: 10 mm, cell volume: 8 µL, equipped with temperature control function) Low-diffusion inert cell (optical path length: 5 mm, cell volume: 2.5 µL, equipped with temperature control function)	
Available pH range	1 to 13 (Cell quartz might be damaged by a mobile phase of pH>10.)	
Dimensions [mm], weight	W 260 × D 500 × H 140 mm, 11 kg	
Operating temperature range	4 to 35 ˚C	
Power supply	AC 100 to 240 V, 150 VA, 50/60 Hz	

*when using inert flow cell for UHPLC analysis

PDA Detector


SPD-M40

	SPD-M40
Light source	Deuterium (D_2) lamp, tungsten lamp
Number of diode elements	1024
Wavelength range	190 to 800 nm
Wavelength accuracy	≤ ±1 nm
Wavelength repeatability	≤ ±0.1 nm
Slit width	1.2 nm, 8 nm
Spectral resolution	≤ ±1.4 nm
Drift*	≦0.4×10^{-3} AU/h (under specified conditions, typically)
Noise*	≦6.0×10^{-6} AU (under specified conditions)
Linearity*	2.5 AU (under specified conditions, typically)
Recommended flow cell	Inert cell (tubing I.D.: 0.3 mm, optical path length: 10 mm, cell volume: 12 µL, equipped with temperature control function) Inert cell for low-pressure-resistant columns (tubing I.D.: 0.5 mm, optical path length: 10 mm, cell volume: 12 µL, not equipped with temperature control function)
Materials of wetted parts	PEEK, PFA, quartz
Sampling rate	Max. 100 Hz (Single wavelength mode)
Cell temperature control range	19 to 50 ˚C, 1 ˚C step
Optional flow cell	UHPLC inert cell (optical path length: 10 mm, cell volume: 8 µL, equipped with temperature control function) Low-diffusion inert cell (optical path length: 5 mm, cell volume: 2.5 µL, equipped with temperature control function)
Available pH range	1 to 13 (Cell quartz might be damaged by a mobile phase of pH>10.)
Dimensions [mm], weight	W 260 × D 500 × H 140 mm, 10 kg
Operating temperature range	4 to 35 ˚C
Power supply	AC 100 to 240 V, 180 VA, 50/60 Hz

*when using inert flow cell for UHPLC analysis

Fluorescence Detectors


RF-20Axs

	RF-20A	RF-20Axs
Light source	Xenon lamp	Xenon lamp Low-pressure mercury lamp (for checking wavelength accuracy)
Wavelength range	200 to 650 nm	200 to 700 nm
Spectral bandwidth	20 nm	
Wavelength accuracy	± 2 nm	
Wavelength precision	± 0.2 nm	
S/N ratio	Water Raman peak with 1200 or higher S/N 9000 or higher S/N when background is low	Water Raman peak with 2000 or higher S/N 12000 or higher S/N when background is low
Cell temperature setting range	—	4 to 40 °C in 1 °C steps
Cell temperature control range	—	10 °C below R.T. to 40 °C
Cell	Inert cell (cell volume: 12 µL, cell pressure resistance: 2 MPa)	
Sampling rate	Max. 100 Hz (1 wavelength mode)	
Functions	Simultaneous measurement of 4 wavelengths and wavelength scanning	
Dimensions [mm], weight	W 260 × D 500 × H 210 mm, 16 kg	W 260 × D 500 × H 210 mm, 18 kg
Operating temperature range	4 to 35 ˚C	
Power supply	AC 100 to 240 V, 400 VA, 50/60 Hz	

Fraction Collector

FRC-10A

	FRC-10A
Max. flow rate	150 mL/min
Fraction modes	Time-based fractionation, peak-based fractionation
Cooling functions	Yes (optional, only for 4 mL vials)
Max. number of supported containers	144 test tubes with 10 mm O.D. 64 test tubes with 18 mm O.D. 16 test tubes with 35 mm O.D. 96 microtubes (1.5 mL, 2 mL) 64 15-mL tubes (centrifuge tubes with 17 mm O.D.) One 96-well plate (with minimum 30 mm plate height)
Dimensions [mm], weight	W 260 × D 320 × H 280 mm, 18.5 kg
Power supply	AC 100 to 240 V, 120 VA, 50/60 Hz

pH monitor

pHM-40

	pHM-40
Available pH range	1 to 14
Precision	pH ±0.1 (under specified conditions)
Drift	pH ±0.1/10 h (under specified conditions)
Maximum flow rate	10 mL/min
Allowable maximum pressure	0.1 MPa
Cell volume	approx. 80 µL
Available liquid temperature	4 to 60 °C
Wetted materials	glass, PEEK, PCTFE, silicon
Calibration point	1 to 5 point is settable.
Dimensions [mm], weight	W 130 × D 393 × H 206, 6 kg
Power supply	DC 5 V, 5 VA

Flow Line Switching Valves (for switching between columns)

FCV-12AHi

FCV-14AHi

	FCV-12AHi	FCV-14AHi
Number of positions	2 positions	6 positions
Number of ports	6 ports	7 ports
Materials of wetted parts	PEEK, ETFE, ceramic	PEEK, polyamide, ceramic
Pressure resistance (when using aqueous mobile phases)	19.6 MPa	
Operating temperature	4 to 35 ˚C	
Number installable inside option box	Max. 2	
Dimensions [mm], weight (option box)	W 260 × D 420 × H 140 mm, 7.3 kg	
Power supply (option box)	AC 100 to 240 V, 70 VA, 50/60 Hz	

*FCV-12Hi and FCV-14Hi are installed inside option box. Operated via control software.

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