

High Performance Liquid Chromatography Columns

Shim-pack HPLC Columns for Bioseparation

CoreFocus





Ion Exchange Chromatography Columns

Shim-pack™ Bio IEX P. 9

Hydrophobic Interaction Chromatography Columns

Shim-pack Bio HIC P. 10

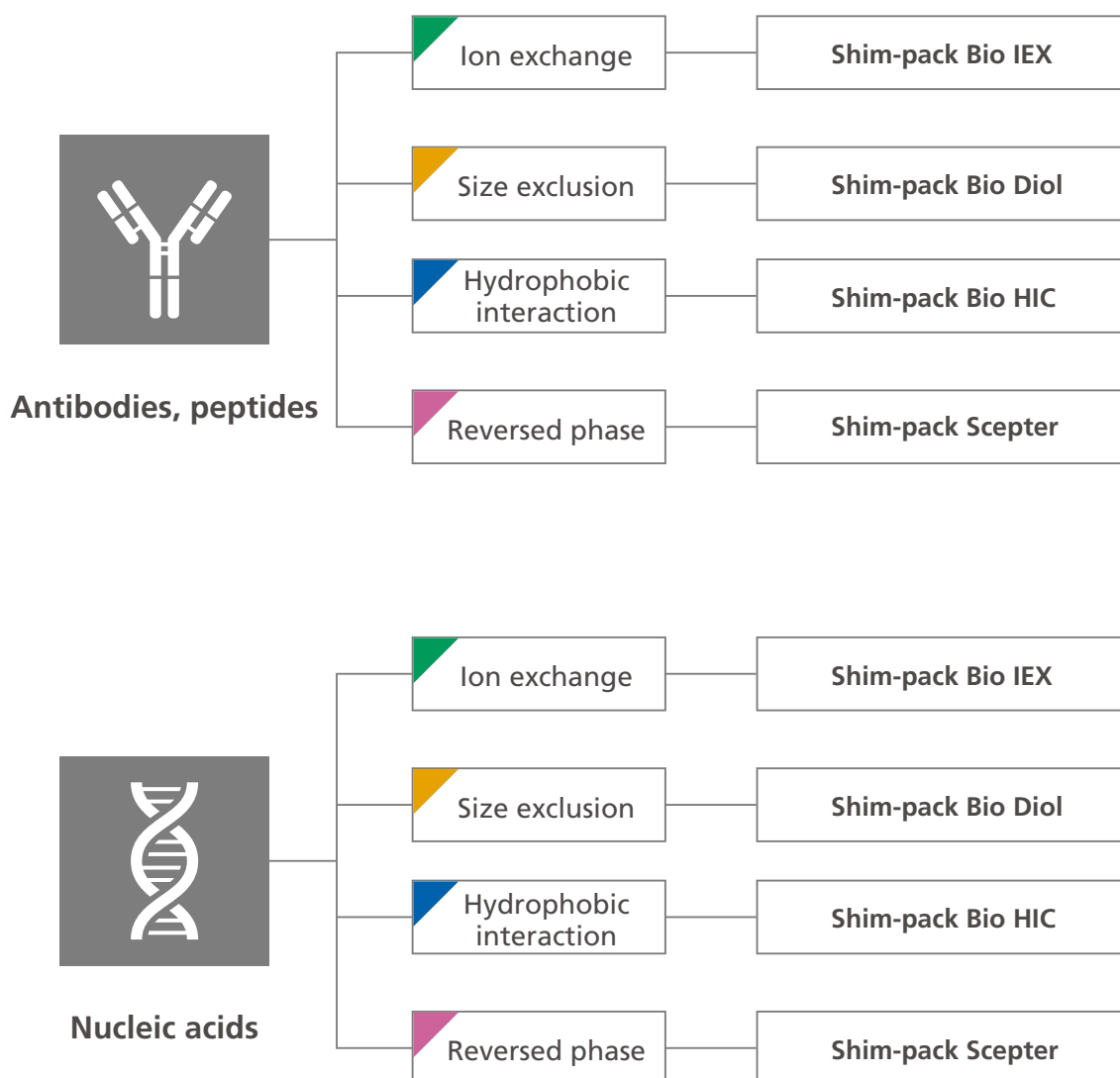
Size Exclusion Chromatography Columns

Shim-pack Bio Diol P. 11

Reversed Phase Chromatography Columns

Shim-pack Scepter™ P. 12

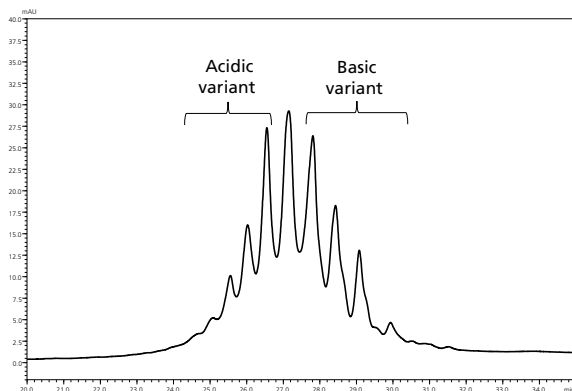
Selection by Target Analytes





Antibody and Peptide Analysis Examples

Charge Variant Analysis of Monoclonal Antibodies –Shim-pack Bio IEX SP-NP –



Conditions

Column : Shim-pack Bio IEX SP-NP
(100 mm × 4.6 mm I.D., 3 μm)
P/N: 227-31005-03

Mobile phase : A) 20 mmol/L MES-HEPES-Sodium Acetate (pH 5.0)
B) 20 mmol/L MES-HEPES-Sodium Acetate (pH 10.6)

Gradient : 0-100 % (0-15 min)→100 % (15-20 min)→
0 % (20.1-30 min)

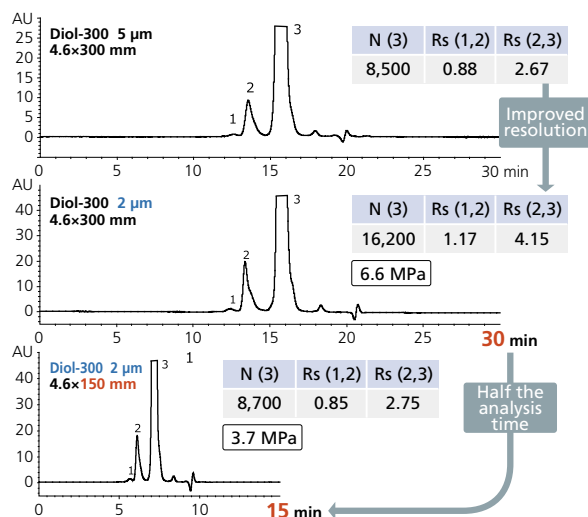
Flow rate : 0.3 mL/min

Column temp. : Ambient

Detection : UV 280 nm

Sample : Cetuximab bio-similar

Analysis of Antibody and Antibody-Drug Conjugate Aggregates by Size Exclusion Chromatography –Shim-pack Bio Diol-300 –



Conditions

Column : Shim-pack Bio Diol-300

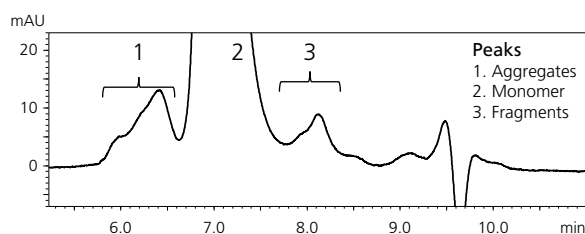
Mobile phase : 0.1 M KH₂PO₄-K₂HPO₄ (pH 7.0) with 0.2 M NaCl

Flow rate : 0.2 mL/min

Column temp. : Ambient

Detection : UV 280 nm

Sample : Humanized monoclonal IgG1



Conditions

Column : Shim-pack Bio Diol-300

Mobile phase : 15 % acetonitrile in
100 mmol/L (sodium) phosphate buffer (pH 6.9)

Flow rate : 0.2 mL/min

Column temp. : 25 °C

Detection : UV 280 nm

Sample : Antibody-drug conjugate standard (1 mg/mL)

Recommended: pHM-40 for mobile phase pH monitoring

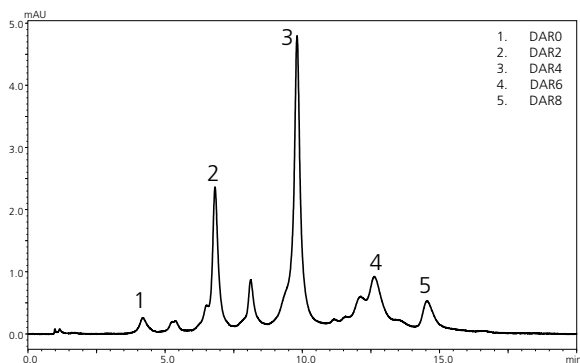
Product



Analysis of ADC Drug Antibody Ratio

–Shim-pack Bio HIC –

ADC DAR Analysis using Shim-pack BIO HIC Column



Conditions

Column : Shim-pack Bio HIC (100 mm. x 4.6 mm I.D., 4 µm)
P/N: 227-31174-01
Mobile phase : A) 50 mM NaH₂PO₄-Na₂HPO₄ (pH 7.0)
containing 1.5 M (NH₄)₂SO₄/2-propanol (95/5)
B) 50 mM NaH₂PO₄-Na₂HPO₄ (pH 7.0)
/2-propanol (80/20)
Gradient : 0 %B (0-1 min), 0-100 %B (1-18 min),
100 %B (18-23 min)
Flow rate : 1.0 mL/min
Column temp. : 25 °C
Detection : 280 nm (PDA)
Sample : Cysteine-like ADC Mimic (5 mg/mL)

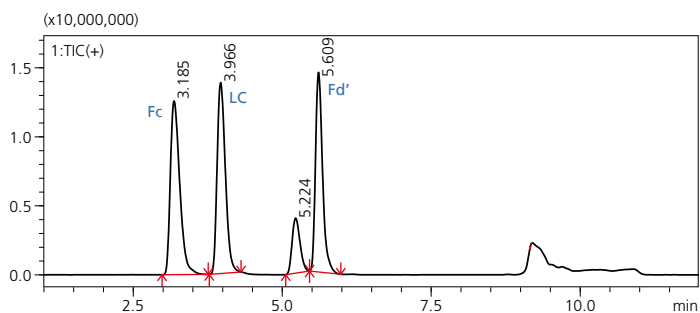
Peak area reproducibility (n = 6)

	%RSD
DAR0	5.98
DAR2	2.57
DAR4	1.62
DAR6	2.23
DAR8	2.87

Note: Peaks integrated automatically using i-PeakFinder™
(unique peak processing algorithm for LabSolutions)

Analysis of Antibody Digests

–Shim-pack Scepter C4 –



Conditions

Column : Shim-pack Scepter C4-300
(50 mmL. x 2.1 mm I.D., 3 µm)
P/N: 227-31176-01
Mobile phases : A) 0.1 % formic acid in water
B) 0.1 % formic acid in acetonitrile
Gradient program : 1 %B (1 min)→25 %B (1.1 min)
→ 40 %B (8 min)
→ 95 %B (8.1 min-10min)
→ 1 %B (10.1-15 min)
Flow rate : 0.3 mL/min
Column temp. : 50 °C
Sample : IdeZ digested + DTT treated
Adalimumab 0.2 mg/mL

► Recommended: LCMS-9050 liquid chromatograph
mass spectrometer for analysis of biologics

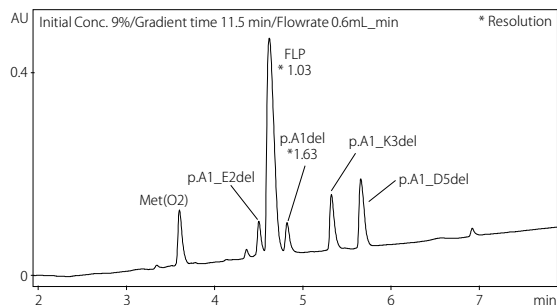
Product





Antibody and Peptide Analysis Examples

■ Separation Analysis for Synthetic Peptide and Related Impurities –Shim-pack Scepter C8-120 –



Conditions

Column : Shim-pack Scepter C8-120
(100 mmL. × 2.1 mm I.D., 3 μm)
P/N: 227-31013-03

Mobile Phases : A) 0.1% formic acid in water
B) Methanol

Gradient Program : 9%B (0 min) -60%B (11.5 min)→
9%B (11.6-20 min)

Flow rate : 0.6 mL/min

Column Temp. : 80 °C

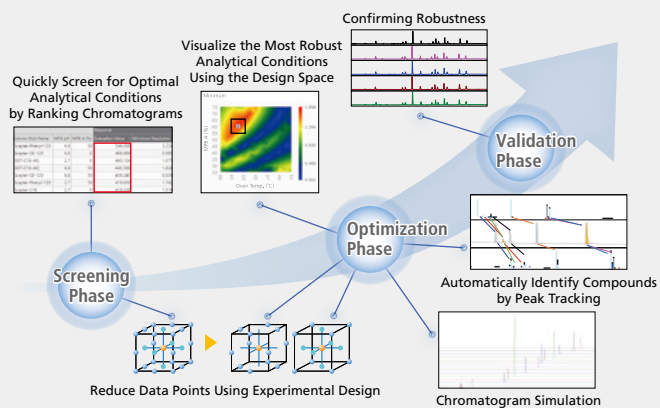
Injection volume : 2 μL

Sample : Refer to the below Table

名称	Sequence
FLP	AEKKDEGPYRMEHFRWGSPPKD
p.A1del	EKKDEGPYRMEHFRWGSPPKD
p.A1_E2del	KKDEGPYRMEHFRWGSPPKD
p.A1_K3del	KDEGPYRMEHFRWGSPPKD
p.A1_D5del	EGPYRMEHFRWGSPPKD
Met(O2)	AEKKDEGPYR{Met(O2)}EHFRWGSPPKD

Application

► Recommended: LabSolutions MD for method development

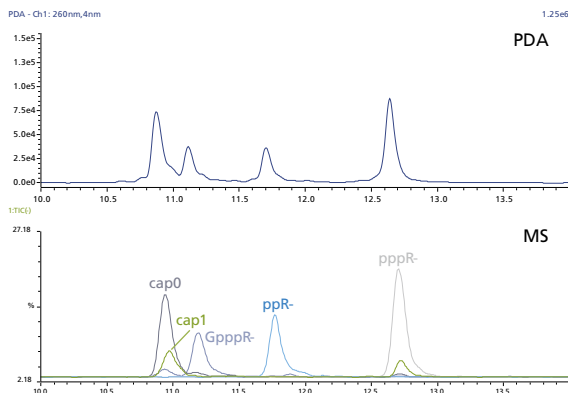


Product



Nucleic Acid Analysis Examples

Efficient Method Development for Separation of Capped mRNA Fragments –Shim-pack Scepter Claris C18-300–



Conditions

Column : Shim-pack Scepter Claris C18-300
(100 mmL. × 2.1 mm I.D., 1.9 μm)
P/N: 227-31209-02

Mobile Phases : A) 100 mmol/L HFIP and 20 mmol/L HA in water
B) Acetonitrile/methanol = 75/25 (v/v)

Gradient Program : 20%B(0-2 min) - 60%B (32 min)→
90%B (32.1-34 min) →20%B (34.1-40 min)

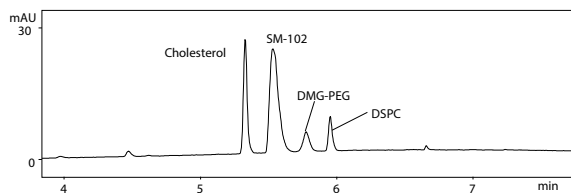
Flow rate : 0.3 mL/min

Column Temp. : 40 °C

Injection volumn : 1 μL

Application

Efficient Method Development of Lipid Nanoparticle Components Using ELSD –Shim-pack Scepter Phenyl-120–



Conditions

Column : Shim-pack Scepter Phenyl-120
(100 mmL. × 3.0 mm I.D., 1.9 μm)
P/N: 227-31064-03

Mobile Phases : A) 0.1% formic acid in water
B) Acetonitrile/Methanol /2-Propanol =
27/63/10 (v/v/v)

Gradient Program : 70% (0min) →95% (4-7min) →
70% (7.01-13min)

Flow rate : 0.6 mL/min

Column Temp. : 50 °C

Injection volumn : 1 μL

<Acknowledgments>

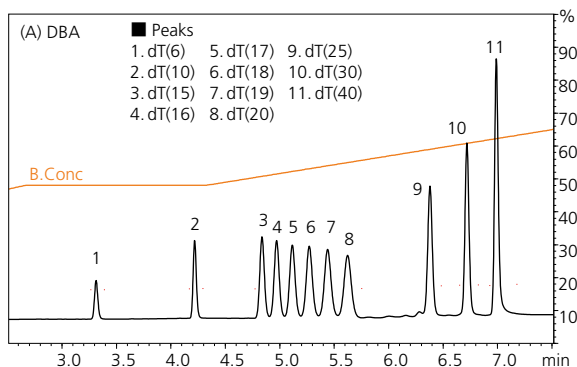
We gratefully acknowledge Dr. Naohiro Tsuyama of the PSI GMP Education and Research Center, Hiroshima University, for kindly providing the sample.

Application



Nucleic Acid Analysis Examples

■ Analysis of Oligonucleotides of Different Chain Length by Ion Pair Reversed Phase Chromatography –Shim-pack Scepter C18-120 [metal free] –



Conditions

Column : Shim-pack Scepter Claris C18-120
(100 mmL. × 2.1 mm I.D., 3 µm)
P/N: 227-31210-05

Mobile Phases : A) 50 mmol/L DBAA (Dibutylamine acetate)
pH7.5
B) Methanol

Gradient Program : Refer to the below table

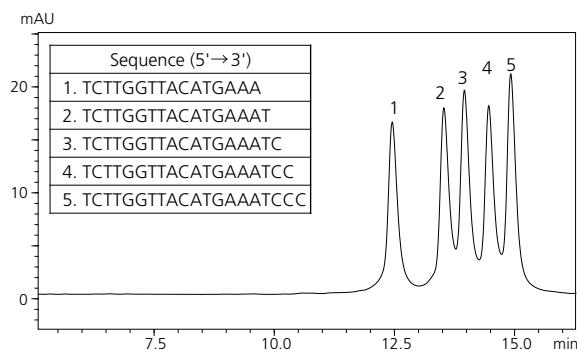
Flow rate : 0.6 mL/min

Column Temp. : 80 °C

Injection volume : 5 µL

DBAA		
Time (min)	A conc.	B conc.
0	70	30
0.35	70	30
1.25	61	39
1.42	61	39
2.67	52	48
4.33	52	48
7.93	32.8	67.2
7.94	0	100
10.93	0	100
10.94	70	30
14.94	70	30

■ Ion Exchange Chromatography of Oligonucleotides –Shim-pack Bio IEX –



Conditions

Column : Shim-pack Bio IEX Q-NP
(100 mmL. × 4.6 mm I.D., 5 µm)
P/N: 227-31003-03

Mobile phases : A) 10 mmol/L NaOH
B) 10 mmol/L NaOH containing 1mol/L NaClO₄

Gradient program : 25 %B (0 min)→32.5 %B (-15 min)→
100 %B (15.1-20 min)→25 % (20.1-25 min)

Flow rate : 0.8 mL/min

Column temp. : 30 °C

Detection : 265 nm (PDA)

Sample : Described in the chromatogram

Column Recommendations for Compound Type

Ion Exchange Chromatography Columns for Protein and Nucleic Acid Analysis

Shim-pack Bio IEX Columns

The Shim-pack Bio IEX columns are available in the following chemistries.

- Anion exchange quaternary ammonium (Q)
- Cation exchange sulfopropyl (SP)

Porous particles and non-porous particles are available, both using hydrophilic polymer packing.

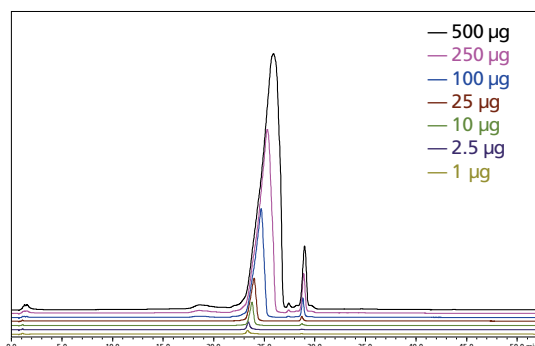
- Hydrophilic porous polymer (Q and SP columns)
- Hydrophilic non-porous polymer (Q-NP and SP-NP columns)

The porous packing materials offer highly efficient and excellent binding capacity, and the non-porous packing materials offer high recovery rates and excellent resolution.

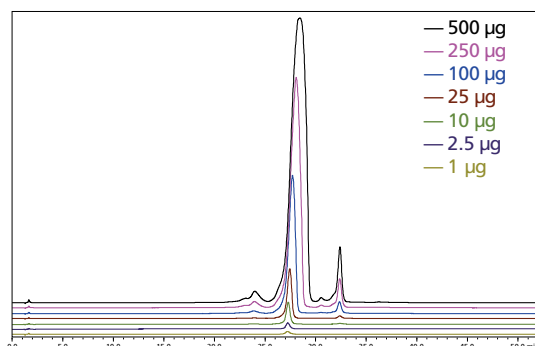
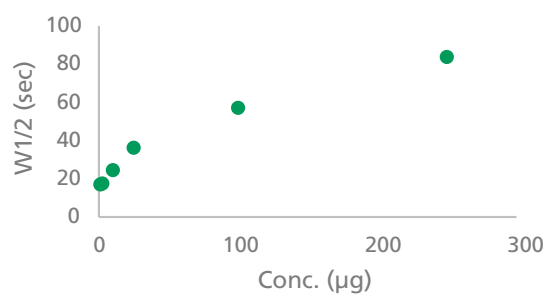
	Q-NP	SP-NP	Q	SP
Particle Material	Hydrophilic non-porous polymer		Hydrophilic porous polymer	
Particle Size	3 μm , 5 μm		5 μm	
Ion Exchange Group	- $\text{CH}_2\text{N}^+(\text{CH}_3)_3$	- $(\text{CH}_2)_3\text{SO}_3^-$	- $\text{CH}_2\text{N}^+(\text{CH}_3)_3$	- $(\text{CH}_2)_3\text{SO}_3^-$
Operating pH Range	2 - 12			
Operating Temp. Range	4-60°C			
Column Material	PEEK			

Differences Between Polar Type and Non-Polar Type Columns

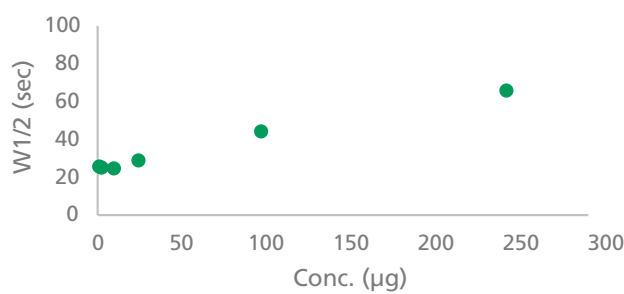
Porous type columns are designed for applications such as protein purification at the lab-scale, where high loading capacity and stable peak widths are essential. On the other hand, non-porous type columns are optimized for impurity analysis requiring high resolution, such as charge variant analysis, offering narrower peak widths at lower loading amounts. The Shim-pack Bio IEX SP-NP, a non-porous type column, and the Shim-pack Bio IEX SP, a porous type column, were used to demonstrate changes in peak width when increasing the loading amount of monoclonal antibodies (shown in below figures).



Shim-pack Bio IEX SP-NP



Shim-pack Bio IEX SP



Column Recommendations for Compound Type

Product Name	P/N	Particle Size	I.D.	Length	Maximum Pressure (MPa)	Specification
Shim-pack Bio IEX Q-NP	227-31002-01	3 μ m	4.6 mm	30 mm	25.0	Non-porous anion exchange
	227-31002-02		4.6 mm	50 mm		
	227-31002-03		4.6 mm	100 mm		
	227-31003-01	5 μ m	4.6 mm	30 mm	6.0	
	227-31003-02		4.6 mm	50 mm	10.0	
	227-31003-03		4.6 mm	100 mm	12.0	
Shim-pack Bio IEX SP-NP	227-31005-01	3 μ m	4.6 mm	30 mm	25.0	Non-porous cation exchange
	227-31005-02		4.6 mm	50 mm		
	227-31005-03		4.6 mm	100 mm		
	227-31006-01	5 μ m	4.6 mm	30 mm	6.0	
	227-31006-02		4.6 mm	50 mm	10.0	
	227-31006-03		4.6 mm	100 mm	12.0	
Shim-pack Bio IEX Q	227-31001-01	5 μ m	4.6 mm	30 mm	2.5	Porous anion exchange
	227-31001-02		4.6 mm	50 mm	3.0	
	227-31001-03		4.6 mm	100 mm	3.5	
Shim-pack Bio IEX SP	227-31004-01	5 μ m	4.6 mm	30 mm	2.5	Porous cation exchange
	227-31004-02		4.6 mm	50 mm	3.0	
	227-31004-03		4.6 mm	100 mm	3.5	

For Analysis of Antibody-Drug Conjugates and Isomers Not Separated by Ion Exchange Chromatography

Shim-pack Bio HIC Columns

The Shim-pack Bio HIC column is a hydrophobic interaction chromatography (HIC) column packed with butyl bonded hydrophilic non-porous polymer particles (4 μ m). HIC is suitable for the separation of analytes with slight differences in hydrophobicity, such as antibody-drug conjugates (ADCs) with different drug-antibody ratios (DARs). Shim-pack Bio HIC can be used to analyze the DAR of ADCs at low back pressures with high resolution.

Product Name	P/N	Particle Size	I.D.	Length	Maximum pressure
Shim-pack Bio HIC Butyl	227-31174-01	4 μ m	4.6 mm	100 mm	20 MPa

► **Recommended: Nexera™ lite inert/Nexera XS inert**
for analysis of antibodies, proteins, and nucleic acids,
with the FRC-40 for purification.

Product



For Analysis of Protein Aggregates and Nucleic Acids of Different Sizes

Shim-pack Bio Diol Columns

Shim-pack Bio Diol columns are size exclusion chromatography columns with packing particles of various pore sizes for analyzing aggregates and fragments of antibodies, oligonucleotides, carbohydrates, and other analytes. The lineup includes 2 μm particle high-speed analysis columns that enable rapid characterization in addition to purification of trace amounts of substances at the laboratory scale.

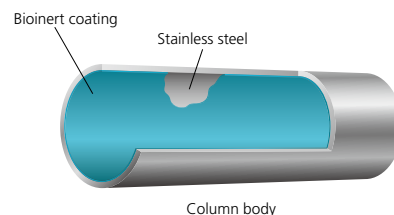
	Diol-60	Diol-120	Diol-200	Diol-300
Particle Material	Silica gel			
Functional Group	Dihydroxypropyl (Diol)			
Particle Size	3 μm , 5 μm		2 μm , 3 μm , 5 μm	
Pore Size	6 nm (60Å)	12 nm (120Å)	20 nm (200Å)	30 nm (300Å)
Operating pH Range	5.0 - 7.5			
Molecular Weight Range	10,000 or less	1,000 - 100,000	5,000 - 300,000	20,000 - 1,000,000
Maximum pressure	2 μm : 45 MPa (Usually at 30 MPa or less)		3, 5 μm : 20 MPa	

Particle Size		2 μm		3 μm				
Chemistry	Column Dimension	Diol-200	Diol-300	Diol-60	Diol-120	Diol-200	Diol-250	Diol-300
	150 × 4.6 mm	227-31009-01	227-31010-01					
	300 × 4.6 mm	227-31009-02	227-31010-02	227-31007-01	227-31008-01	227-31009-03	227-31216-01	227-31010-03
	300 × 8.0 mm	-	-	-	-	-	227-31216-02	-
	10 × 4.0 mm (Guard Column)	227-31202-02	227-31202-01	-	-	227-31202-04	-	227-31202-03
	Pressure Tolerance (MPa)	45		20			4.6 mm I.D. : 14 8.0 mm I.D. : 12	
	20							
Particle Size		5 μm						
Chemistry	Column Dimension	Diol-60	Diol-120	Diol-200	Diol-300			
	300 × 4.6 mm	227-31007-02	227-31008-02	227-31009-04	227-31010-04			
	300 × 8.0 mm	227-31007-03	227-31008-03	227-31009-05	227-31010-05			
	30 × 8.0 mm (Guard Column)	227-31007-04	227-31008-04	227-31009-06	227-31010-06			
	Pressure Tolerance (MPa)	20						
	300 × 20 mm	227-31097-01	227-31098-01	227-31099-01	227-31100-01			
	500 × 20 mm	227-31097-02	227-31098-02	227-31099-02	227-31100-02			
	50 × 20 mm (Guard Column)	227-31116-01	227-31118-01	227-31118-01	227-31119-01			
	Pressure Tolerance (MPa)	10						

Shim-pack Scepter Claris

Chemistry		C18-120			C18-300			C8-120		
Particle Size (μm)	ID (mm)	2.1	3	4.6	2.1	3	4.6	2.1	3	4.6
	Length (mm)									
1.9	50	227-31210-01	-	-	227-31209-01	-	-	227-31212-01	-	-
	75	-	-	-	-	-	-	-	-	-
	100	227-31210-02	-	-	227-31209-02	-	-	227-31212-02	-	-
	150	227-31210-03	-	-	227-31209-03	-	-	227-31212-03	-	-
3	50	227-31210-04	-	227-31210-07	227-31209-04	-	227-31209-07	227-31212-04	-	227-31212-07
	75	-	-	-	-	-	-	-	-	-
	100	227-31210-05	-	227-31210-08	227-31209-05	-	227-31209-08	227-31212-05	-	227-31212-08
	150	227-31210-06	-	227-31210-09	227-31209-06	-	227-31209-09	227-31212-06	-	227-31212-09
5	250	-	-	-	-	-	-	-	-	-
	50	227-31210-10	-	227-31210-13	227-31209-10	-	227-31209-13	227-31212-10	-	227-31212-13
	75	-	-	-	-	-	-	-	-	-
	100	227-31210-11	-	227-31210-14	227-31209-11	-	227-31209-14	227-31212-11	-	227-31212-14
5	150	227-31210-12	-	227-31210-15	227-31209-12	-	227-31209-15	227-31212-12	-	227-31212-15
	250	-	-	-	-	-	-	-	-	-

Chemistry		C4-300			Phenyl		
Particle Size (μm)	ID (mm)	2.1	3	4.6	2.1	3	4.6
	Length (mm)						
1.9	50	227-31208-01	-	-	227-31215-01	-	-
	75	-	-	-	-	-	-
	100	227-31208-02	-	-	227-31215-02	-	-
	150	227-31208-03	-	-	227-31215-03	-	-
3	50	227-31208-04	-	227-31208-07	227-31215-04	-	227-31215-07
	75	-	-	-	-	-	-
	100	227-31208-05	-	227-31208-08	227-31215-05	-	227-31215-08
	150	227-31208-06	-	227-31208-09	227-31215-06	-	227-31215-09
5	250	-	-	-	-	-	-
	50	227-31208-10	-	227-31208-13	227-31215-10	-	227-31215-13
	75	-	-	-	-	-	-
	100	227-31208-11	-	227-31208-14	227-31215-11	-	227-31215-14
5	150	227-31208-12	-	227-31208-15	227-31215-12	-	227-31215-15
	250	-	-	-	-	-	-



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