S-BPH-B18

SHIMADZU
Excellence in Science

Better Bioseparations with Shimadzu LC Columns

Contents Page

Introduction

Importance of Analytical Techniques in Biopharmaceuticals Analysis

Biopharmaceuticals are medicines and drugs developed using biological means (e.g. in living cells). These drugs are generally high in molecular weight, unstable, immunogenic and possess complex and heterogeneous structures; These drugs include proteins, nuclei acids, and antibodies. With multiple stages in the biopharma workflow (Figure 1), industries must take into consideration various factors to optimize their strategy and operations. Ultimately, the safety and efficacy of the drug, and the speed and cost-efficiency of the entire workflow are key objectives of biopharma industries.

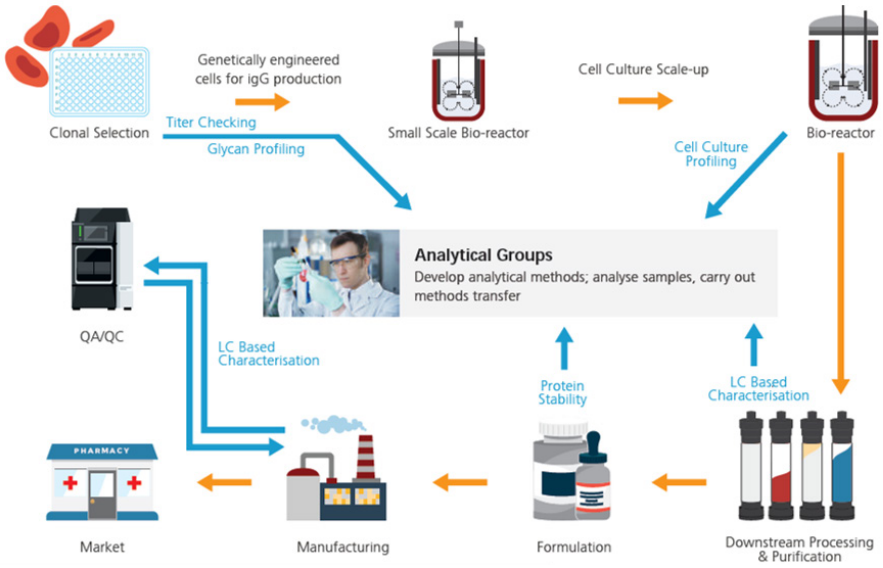


Figure 1: Biopharmaceuticals Workflow and Critical Quality Attributes (CQAs)

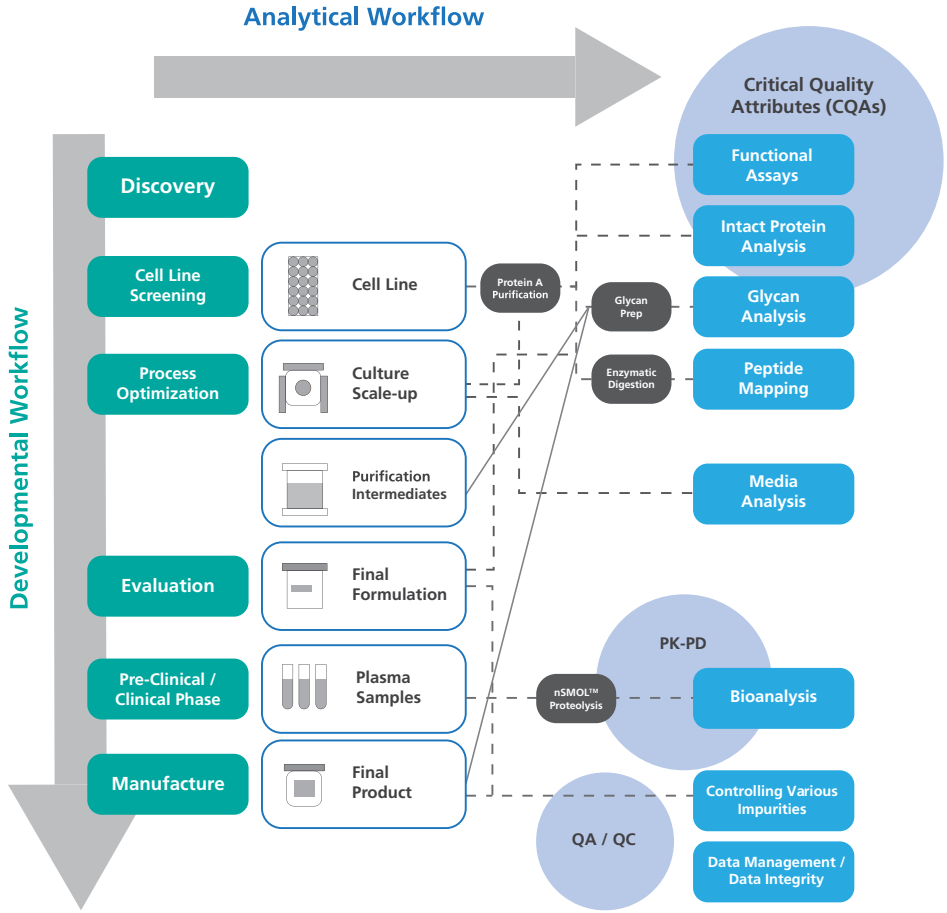


Figure 2: Analytical techniques and characterization of biopharmaceuticals are required in different developmental stages as depicted in this workflow - from cell line screening to manufacturing and quality control.

Introduction

There are several challenges that biopharma industries face. To overcome them and seize the opportunities, industries must tap on various technologies to meet the biopharmaceuticals production and quality control standards, and also to accelerate their drug discovery, development, and compliance processes. Advanced analytical techniques such as chromatography, spectroscopy and mass spectrometry are commonly used by biopharma industries for this purpose.

Liquid chromatography (LC) has been the technique of choice due to its relevance, wide applicability, and efficiency. With advancements in LC columns and instruments, LC analytical methods are shorter in analysis time, better in separation, and higher in signal intensity and sensitivity. In this brochure, you will learn more about the new Shimadzu LC columns and how they are applied in various biopharma workflows. Read on to understand how these LC columns, with Shimadzu LC and mass spectrometry (MS) work together to achieve fast, robust, and reliable separation and measurement.

Figure 3: Shimadzu's Advanced i-Series LC-2050C

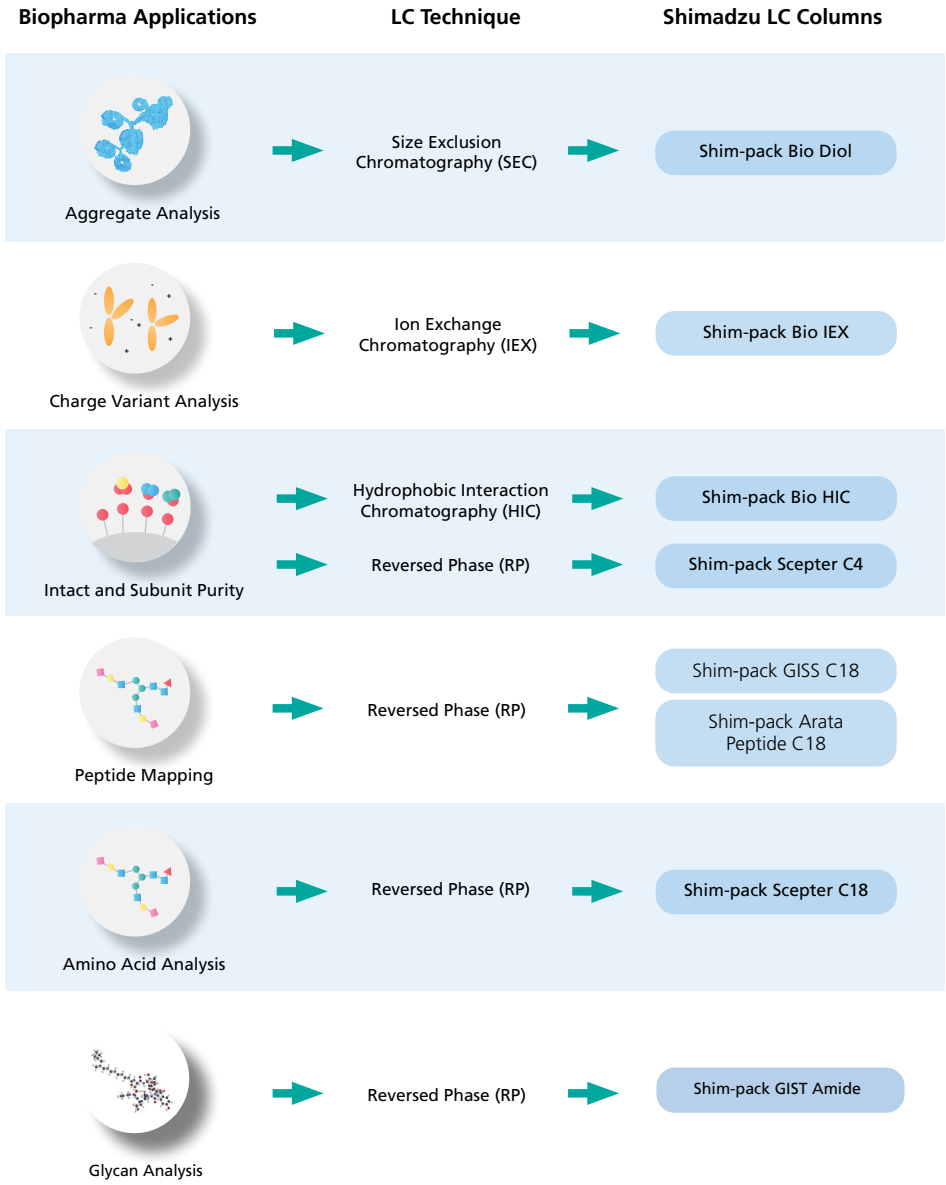


Figure 4: Types of Biopharma Applications With Corresponding LC Techniques and Shimadzu LC Columns

Application Feature

1. Size Exclusion Chromatography (SEC) for Aggregate and Fragment Analysis

SEC separates molecules by size and molecular weight. It has been the main technique for the characterization of protein-based therapeutic products (e.g. monoclonal antibodies, mAbs) due to its speed and reproducibility. As protein aggregation renders the drug to be unsafe and ineffective, the analysis of these undesirable protein aggregates and also fragments could indicate the applicability and efficacy of the produced therapeutic drugs. Typically, SEC coupled to UV detection is used to analyze aggregation and conformational variants in order to monitor the integrity of the investigated drug sample.

1.1 Type of Column Used

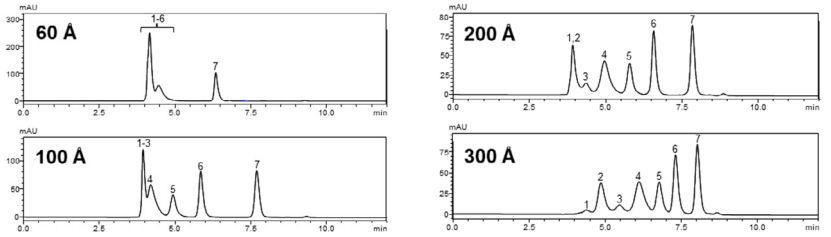
Shim-pack Bio Diol Column

Shim-pack Bio Diol	Diol-60	Diol-120	Diol-200	Diol-300
Particle	Silica			
Ligand	Dihydroxypropyl (Diol)			
Particle Size	3 µm, 5 µm		2 µm, 3 µm, 5 µm	
Pore Size	6 nm	12 nm	20 nm	30 nm
pH Range	5.0 - 7.5			
Molecular Weight Range	below 10,000	1,000 - 100,000	5,000 - 300,000	20,000 - 1,000,000

1.2 Key Results and Chromatograms

1.2.1 Effect of Pore Size on the Separation of Biomolecules

With different pore sizes (6, 12, 20 and 30 nm), Shim-pack Bio Diol SEC columns are able to effectively separate molecules of a wide range of molecular weights.

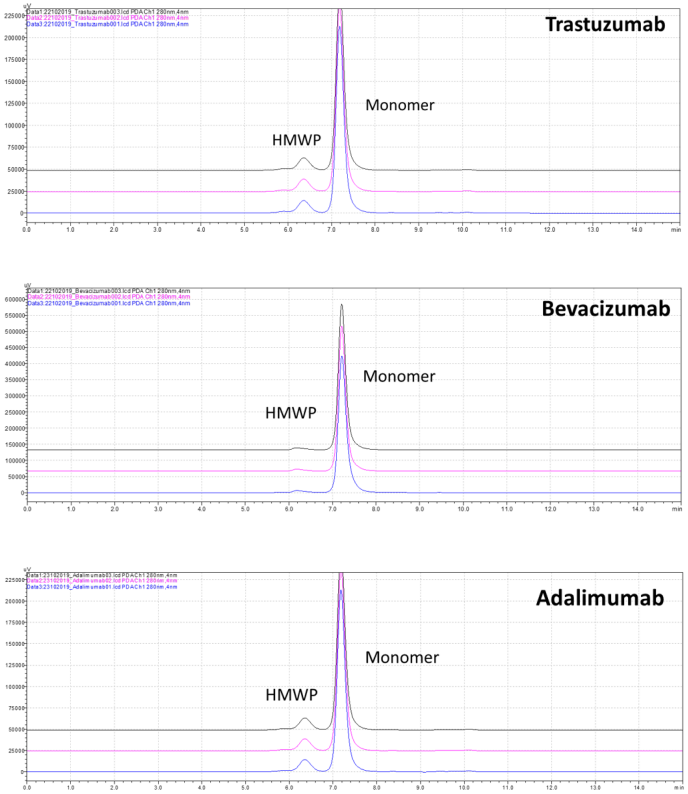


Peak	Component	Estimated Molecular Weight
1-3	Thyroglobulin (Bovine)	670,000 Da
4	γ-Globulin (Bovine)	158,000 Da
5	Ovalbumin (Chicken)	44,000 Da
6	Myoglobin (Horse)	17,000 Da
7	Vitamin B12	1,350 Da

Application Feature

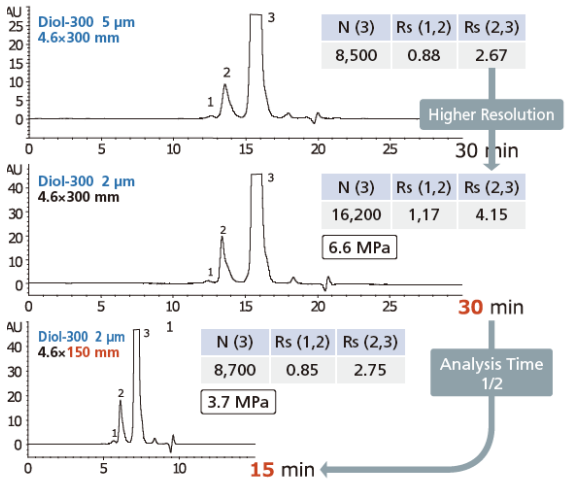
1.2.2 Segregate Analysis of Several mAbs using Shim-pack Bio-Diol 300

The segregate analysis of trastuzumab, bevacizumab, and adalimumab were separately performed using Shimadzu Shim-pack Bio-Diol 300. Sharp peak shapes, good baseline separation, excellent peak stability, and repeatability were demonstrated for all mAbs.



1.2.3 Rapid mAb Aggregate Analysis using 2µm Shim-pack Diol-300 column

Various Shim-pack Bio Diol columns were evaluated for the analysis of humanized monoclonal IgG1. The column of choice demonstrates a shorter separation with sufficient peak separation to simultaneously achieve high resolution and high throughput.



Column	: Shim-pack Bio Diol-300
Eluent	: 0.1 M KH_2PO_4-K_2HPO_4 (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

Application Feature

2. Charge Variant Analysis using Ion Exchange Chromatography (IEX) Analysis

Proteins consist of many weak acidic and basic groups which can undergo changes in charge heterogeneity during biopharmaceutical production and purification processes. These not only affect the stability, but also the activity of the drugs and may cause adverse immunological reactions.The identification of charge variants in development, and their monitoring throughout manufacturing, is critical to the production of safe and effective drugs. IEX utilizes the unique relationship between the net surface charge of the protein and pH for optimal protein separation. The pH or salt concentration defines the number of charges on the protein and helps to stabilize the native structure of the protein in the buffer used during analysis.

2.1 Type of Column Used

Shim-pack Bio IEX Column

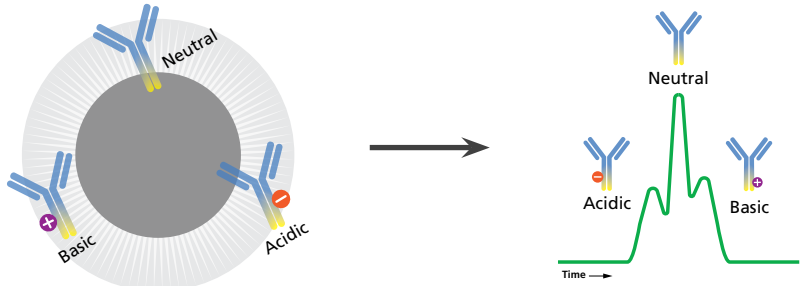
Shim-pack Bio IEX	Q-NP	SP-NP	Q	SP
Particle	Hydrophilic non-porous polymer		Hydrophilic porous polymer	
Particle Size	3 µm, 5 µm		2 µm, 3 µm, 5 µm	
Ligand	- $CH_2N^+(CH_3)_3$	- $(CH_2)_3SO_3^-$	- $CH_2N^+(CH_3)_3$	- $(CH_2)_3SO_3^-$
pH Range	2 - 12			

Q: Quaternary Ammonium | SP: Sulfopropyl | NP: Non-Porous | P: Porous

2.2 Key Results and Chromatograms

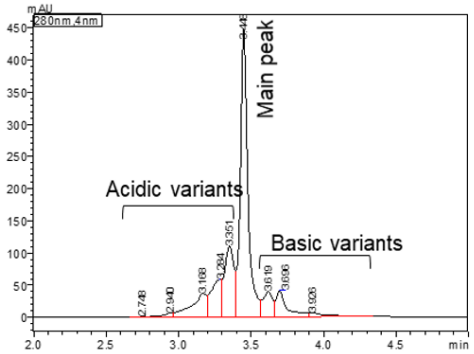
2.2.1 Charge Variant Analysis of mAbs Biosimilars using Shim-pack Bio IEX Column

Cation exchange chromatography (CEX) is widely used as many therapeutic mAbs have a basic isoelectric point. In CEX, acidic species elute earlier followed by neutral then basic species. Both salt- and pH- gradient methods are investigated for the analysis of charge variants of bevacizumab biosimilar using Shim-pack Bio IEX SP-NP column.

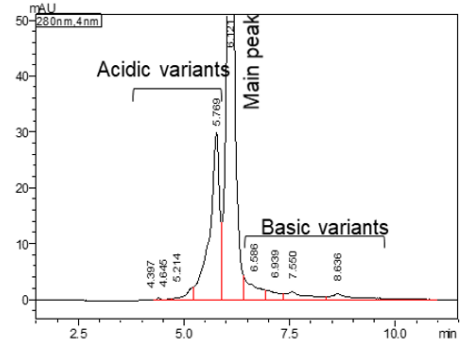


Application Feature

Salt-gradient

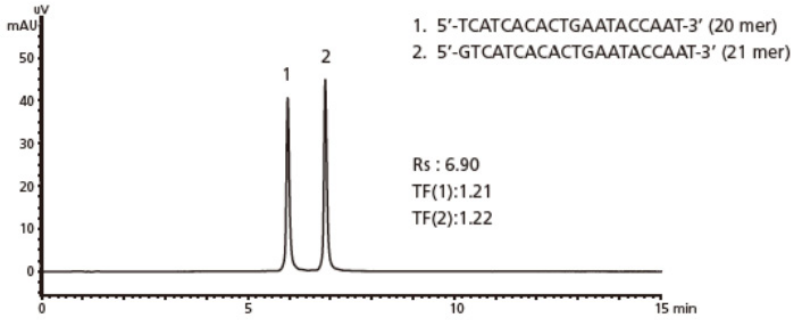


pH-gradient



2.2.2 Analysis of Synthesized Oligonucleotides using Shimadzu Bio IEX Q-NP

Accurate analysis of biopharmaceuticals compounds is necessary to improve its quality. With Shim-pack Bio IEX columns, high accuracy can be achieved in the characterization of peptides, oligonucleotides, and biopharmaceuticals.



Column	: Shim-pack Bio IEX Q-NP 5µm, 4.6 x 100 mm (P/N: 227-31003-03)
Mobile Phase A	: 10 mM NaOH
Mobile Phase B	: 10 mM NaOH with 1.0 M $NaClO_4$
Gradient	: 25 → 55%B (0-15 min), 100%B (15-20 min)
Flow Rate	: 1.0 mL/min
Column Temp.	: 25°C
Detection	: UV, 260 nm
Inj. Volume	: 4 µL (5 nmol/mL)

Application Feature

3. Intact Mass Analysis by Hydrophobic Interaction Chromatography (HIC)

HIC separates analytes based on its hydrophobic interactions with the column stationary phase. The separation occurs in less denaturing conditions and allows the proteins to maintain their biological activity, which is useful for protein separation and purification. For biopharma applications, HIC is suitable for the separation of antibody-drug conjugates (ADCs) with different drug-antibody ratios (DAR). Shim-pack Bio HIC columns can analyze DAR of ADC with relatively low pressure and high resolution.

3.1 Type of Column Used

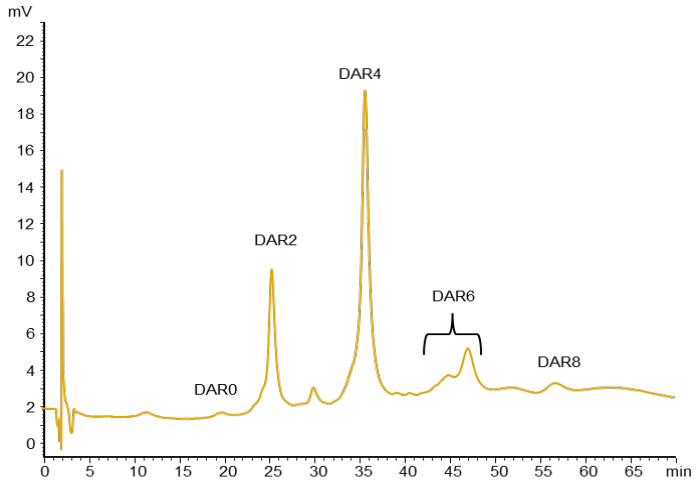
Shim-pack Bio HIC Column

	Shim-pack Bio HIC*
Particle	Hydrophilic non-porous polymer
Particle Size	4 µm
Ligand	Butyl group
pH Range	2 - 12
Temp. Range	10 - 60°C

* It is packed with rigid and non-porous particles, and optimized for high throughput separation of mAbs, ADCs, and other proteins.

3.2 Key Results and Chromatograms

3.2.1 Evaluating DAR Analysis of ADCs

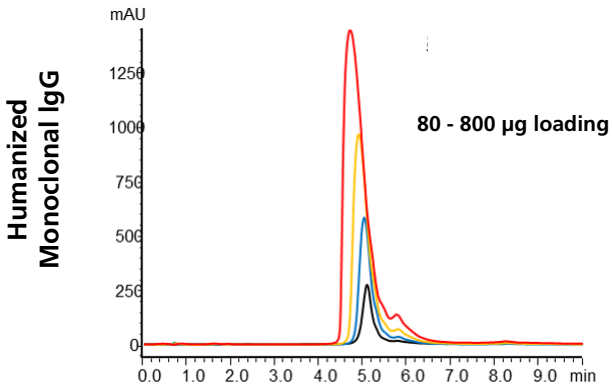


ADCs with different DAR have only slightly different hydrophobic properties. With Shim-pack Bio HIC, high separation capacity can be achieved which allows for the DAR of ADCs to be analyzed easily.

Eluent	A) 50 mM NaH_2PO_4-Na_2HPO_4 (pH 6.8) containing 1.5 M $(NH_4)_2SO_4$ / IPA (95/5) B) 50 mM NaH_2PO_4-Na_2HPO_4 (pH 6.8) / IPA (80/20) 30%B (0-5 min), 30-80%B (5-45 min), 80%B (45-70 min)
Flow Rate	0.4 mL/min
Col. Temp.	25°C
Detection	UV at 280 nm
Inj. Vol.	20 µL
Samples	Cystein-conjugated ADC mimic (1.25 mg/mL)

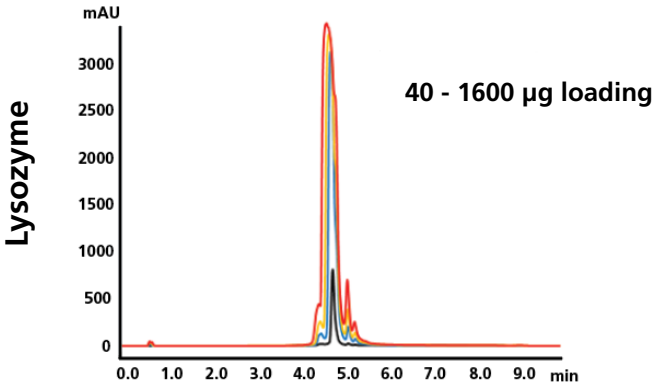
3.2.2 Evaluating the Performance of Shim-Pack Bio HIC Column For High Column Loadability

a) IgG



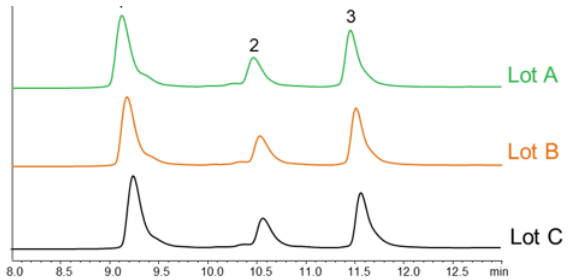
Eluent	: A) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) with 0.2 M $(NH_4)_2SO_4$
	: B) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) 60%B (0 - 0.5 min), 60-100%B (0.5 - 7.5 min), 100%B (7.5 - 10 min)
Temp.	: 30°C
Detection	: UV, 280 nm
Inj Vol.	: 32, 80, 160, 320 µL
Samples	: Humanized monoclonal IgG (2.5 mg/mL)

b) Lysozyme



Eluent	: A) 0.1M NaH_2PO_4-Na_2HPO_4 (pH 7) with 0.2 M $(NH_4)_2SO_4$
	: B) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) 0 - 100%B (0 - 4.58 min), 100%B (4.58 - 6.58 min)
Temp.	: 25°C
Detection	: UV, 280 nm
Inj. Vol.	: 4, 40, 80, 160 µL
Samples	: Lysozyme (10 mg/mL)

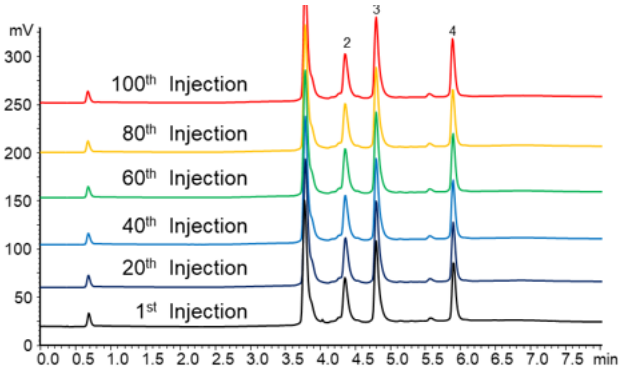
c) Lysozyme, Proteins and Nucleosides



Lot-to-lot reproducibility was investigated for Shim-pack Bio HIC column. Excellent reproducible results were achieved between the three different lots with minimal change in peak intensity, peak shape, and retention time.

Eluent	: A) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) with 0.2 M $(NH_4)_2SO_4$: B) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) 0-100%B (0 - 11 min), 100%B (11 - 15 min)
Flow Rate	: 0.5 mL/min
Temp.	: 25 °C
Detection	: UV, 280 nm
Inj Vol.	: 15 µL
Samples	: 1. Myoglobin (0.73 mg/mL) 2. RNA (0.75 mg/mL) 3. Lysozyme (0.25 mg/mL)

d) Enzymes, Proteins and Nucleosides



Shim-pack Bio HIC Column displays high column stability even after 100 injections. There is no shift in retention time and no changes to the peak shape or intensity were observed for all samples injected.

Eluent	: A) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) with 0.2 M $(NH_4)_2SO_4$: B) 0.1 M NaH_2PO_4-Na_2HPO_4 (pH 7) 0-100%B (0 - 4.58 min), 100%B (4.58 - 6.25 min)
Flow Rate	: 1.2 mL/min
Temp.	: 25 °C
Detection	: UV, 280 nm
Inj Vol.	: 15 µL
Samples	: 1. Myoglobin (0.73 mg/mL) 2. RNA (0.75 mg/mL) 3. Lysozyme (0.25 mg/mL) 4. α-Chymotrypsin A (0.25 mg/mL)

Application Feature

4. Shim-pack Scepter (Reversed Phase Column) for Intact mAbs Characterization

Monoclonal antibodies (mAbs) currently represent the largest class of therapeutic drugs made by the biopharma industry and will play a significant role in the future of pharmacological disease interventions. Purification, characterization and monitoring of mAbs are critically important to drug development, with a variety of analysis techniques routinely used.

Due to the heterogeneity in hydrophobic structure of mAbs, reversed-phase LC separation is becoming a key choice for monitoring purity and stability during manufacturing, formulation and storage. Shimadzu offers reliable solutions for identifying and quantifying degradation products, and monitoring them throughout production and formulation, using LC systems, and MS for quantitation, and/or high-resolution accurate mass analysis.

4.1 Type of Column Used

Shim-pack Scepter C4 Column

	Shim-pack Scepter C4 Column
Particle	Organic Silica hybrid
Ligand	Butyl group
End-capping	Yes
Particle Size	1.9 µm, 3 µm, 5 µm
pH range	1 - 10
Temp. range	Up to 90°C (pH 1 - 7) Up to 50°C (pH 7 - 10)
USP Code	L26

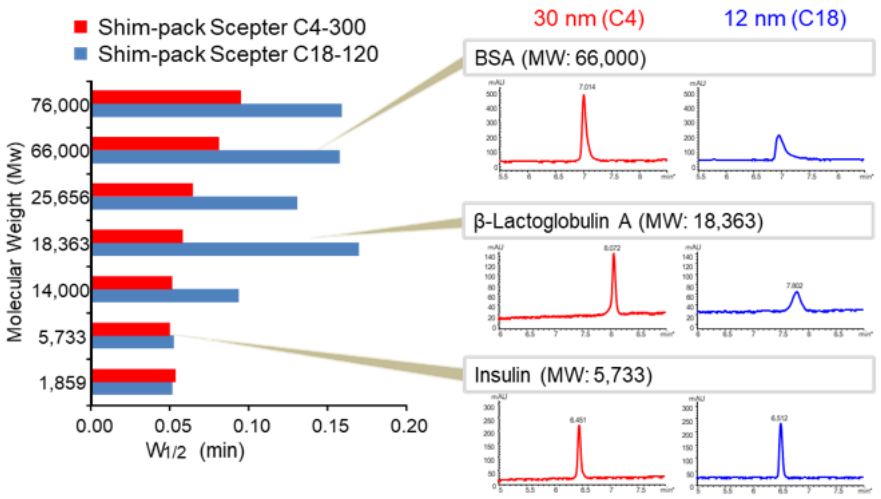
4.2 Key Results and Chromatograms

4.2.1 Evaluating the Performance of Shim-pack Scepter C4 Column

The column is designed to support biomolecules analysis (e.g. proteins) with MW up to 150,000. The hybrid organic silica substrate material allows the separation of mAbs under acidic and high temperature of up to 90°C. Excellent peak shape is achieved even when using low ionic mobile phase (MS compatible conditions). For this reason, Shim-pack Scepter columns can also be used for high sensitivity analysis in LC-MS.

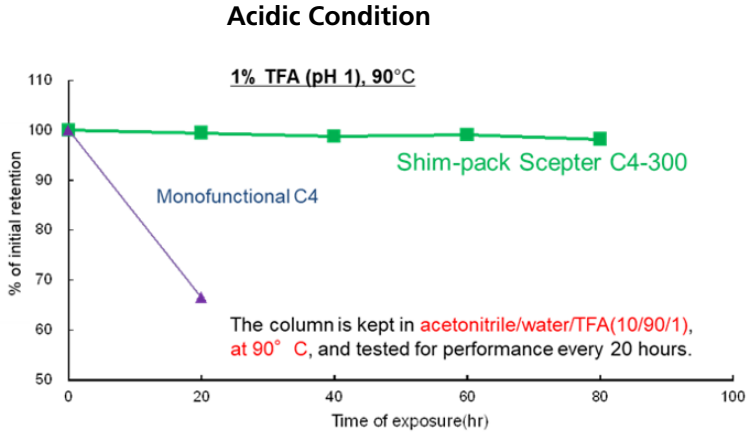
Application Feature

a) Designed for high MW biomolecules



Column	: 150 x 3.0 mm I.D., 5 µm
Eluent	: A) Water / TFA (100/0.1) B) Acetonitrile / TFA (100/0.1) 10 - 95%B (0 - 15 min)
Flow Rate	: 0.4 mL/min
Temp.	: 40°C
Detection	: UV, 220 nm
Inj. Volume	: 4 µL (0.1 ~ 0.5 mg/mL)
Samples	: γ - Endorphin, Insulin, Lysozyme, β- Lactoglobulin A, α-Chymotrypsin A, BSA, Transferrin

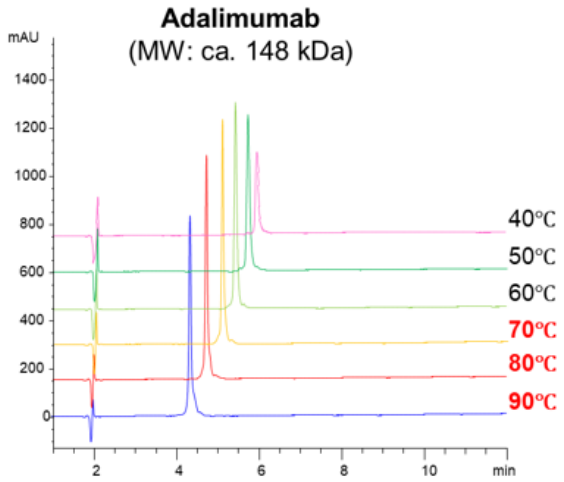
b) High Chemical Stability



Column	: Shim-pack Scepter C4, 150 x 3.0 mm I.D., 5 µm
Eluent	: Acetonitrile / Water (60 / 40)
Flow Rate	: 0.4 mL/min
Samples	: Butyl benzoate

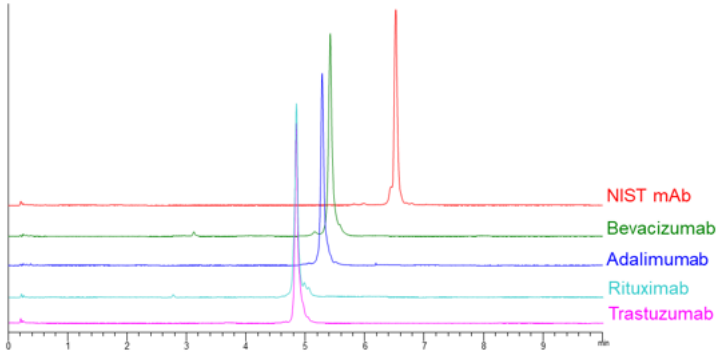
Application Feature

c) High Temperature Stability



Column	: Shim-pack Scepter C4 150 x 3.0 mm I.D., 3 µm
Eluent	: A) Water / TFA (100/0.1) B) Acetonitrile / TFA (100/0.1) 30 - 60%B (0 - 15 min), 90%B (15 - 30 min)
Flow Rate	: 0.4 mL/min
Detection	: UV, 220 nm
Inj. Volume	: 4 µL
Samples	: 0.5 mg/mL

Using Shim-pack Scepter C4 for mAbs characterization, the analysis is highly stable and reproducible with virtually no carryover. The separation of various mAbs using Shim-pack Scepter C4 column is shown below.



Column	: Shim-pack Scepter C4 50 x 2.1 mm I.D., 1.9 µm
Eluent	: A) Water / TFA (100/0.1) B) Acetonitrile / TFA (100/0.1) 25 - 45%B (0 - 10 min)
Flow Rate	: 0.4 mL/min
Temp	: 80°C
Detection	: UV, 280 nm
Inj. Volume	: 2 µL

Application Feature

5A. Tackle Peptide Mapping with Reversed Phase Chromatography

Comprehensive protein characterization is crucial for the biotherapeutics quality control, process monitoring, and more. It involves the detection and monitoring of single amino acid changes, modifications, and degradation products. Peptide mapping is an essential technique for studying the primary structure of proteins and it typically involves enzymatic digestion of protein, followed by chromatographic separation. This technique has become much more convenient and used as a method of choice in many biopharma analysis and workflows.

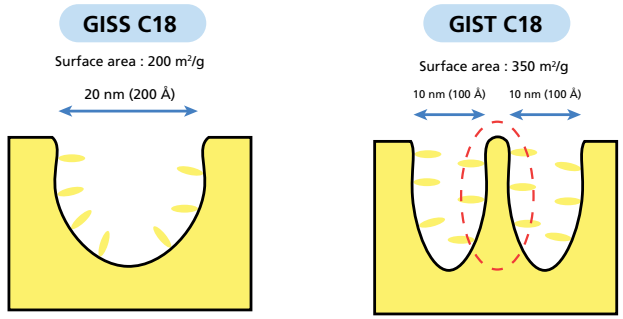
Shimadzu offers a comprehensive portfolio of solutions for the highly accurate confirmation of protein sequence, identification of modifications, and routine protein fingerprint monitoring for QA/QC, using LC systems and columns, LC-MS systems and MALDI-MS platforms.

5.1 Type of Column Used

Shim-pack GISS C18 Column

With its large pore size, the RP column can accommodate a wide range of peptides. It demonstrates low retentivity, high-throughput, and rapid equilibration of mobile phase gradient, making peptide mapping analysis easier.

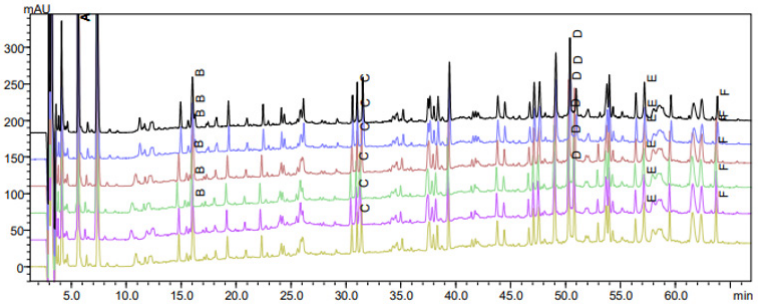
Shim-pack GISS C18	High-speed analysis with ultra high inertness and durability
Bonded Phase	C18 Octadecyl Group
Particle Size	1.9 µm, 3 µm, 5 µm
Pore Size	200 Å
Surface Area	200 m^2 / g
Carbon Loading	9%
End-capped	Yes
pH Range	1 -10
Maximum Temperature	60°C
USP Code	L1



5.2 Key Results and Chromatograms

5.2.1 Peptide Mapping of mAbs for Full Sequence Confirmation

Peptide mapping of enzymatic digest is carried out with Shim-pack GISS C18 RP column and Nexera Bio. High column reproducibility is observed as shown in the inter-day repeatability tests of IgG tryptic digest. High resolution accurate mass spectrometer (LCMS-9030) is employed for protein sequence confirmation.

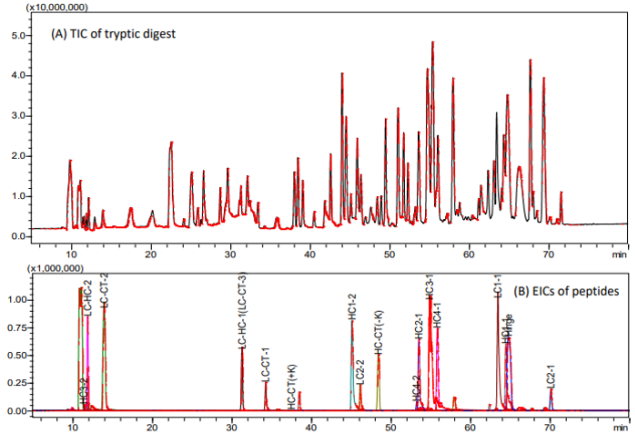


Peak	Average (min)	Std. Dev. (min)	RSD (%)
Peak A	5.618	0.025	0.438
Peak B	16.024	0.077	0.482
Peak C	31.001	0.045	0.146
Peak D	50.318	0.064	0.127
Peak E	57.154	0.036	0.063
Peak F	63.744	0.071	0.111

Download the app note to find out the exact LC column and conditions. Learn more on the column and instrument performance for the primary structure characterization of mAbs and biosimilars.

5.2.2 Characterization of C-terminal and Disulfide Bond Peptides of mAbs (Bevacizumab)

Peptide mapping and sequencing analysis of C-terminal and disulfide-bonds linked peptides are among the essential attributes for characterization of biosimilars. Digested peptides are separated by Shim-pack GISS C18 column and determined by Q-TOF MS.



All three C-terminal peptides as well as cysteine containing peptides expected from bevacizumab biosimilar are successfully identified on the extract mass chromatogram with accurate masses within 2 ppm. Download the app note to get the exact LC conditions and know more about the column and instrument performance.

Application Feature

5B. Tackle Peptide Mapping With Reversed Phase Chromatography

5.1 Type of Column Used

Shim-pack Arata Peptide C18

Shim-pack Arata Peptide C18	Unprecedented Resolution and Peak Shape for Basic Compounds
Bonded Phase	C18 Octadecyl Group
Particle Size	2.2 µm, 5 µm
Pore Size	120 Å
Surface Area	340 m^2 / g
Carbon Loading	17%
End-capped	Yes
pH Range	2 - 7.5
Maximum Temperature	80°C

This column separates well even under formic acid mobile phase, which is suitable for use in LC-MS conditions.

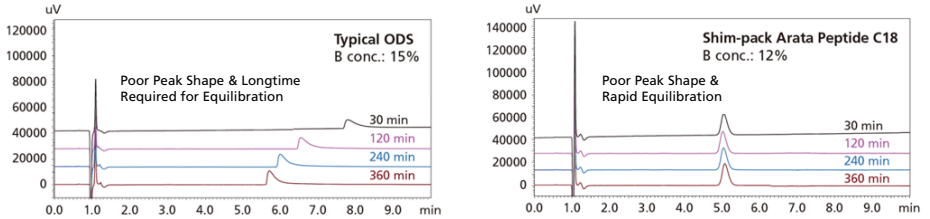
5.2 Key Results and Chromatograms

5.2.1 Increased Assurance of Peptide Analysis

Shim-pack Arata Peptide C18 columns are further tested with a mixture of peptide standards, ensuring consistent column performance and reproducibility for regulatory requirements.

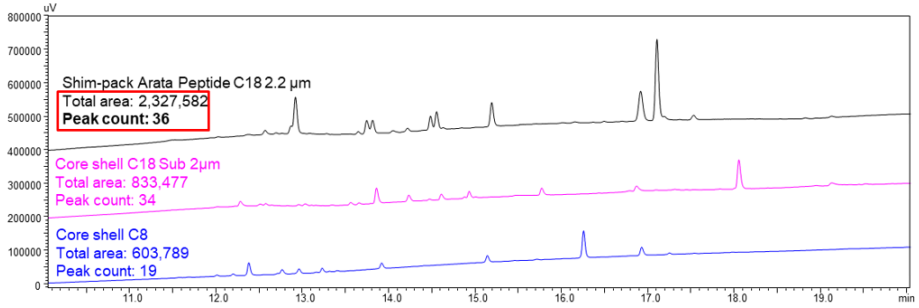
5.2.2 Excellent Peak Shape and Rapid Column Equilibrium

Even in low ionic strength acidic mobile phase, the analysis of Angiotensin I using Shim-pack Arata Peptide C18 column demonstrates excellent separation performance and equilibrium, making peptide mapping analysis more efficient.



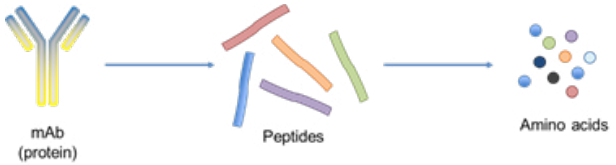
5.2.3 High Peptide Recovery

Peptides can adsorb non-specifically to the column stationary phase resulting in peptide loss and poor separation. However, with Shim-pack Arata Peptide C18 column, this adsorption is not observed and demonstrates high recovery of peptides.



Application Feature

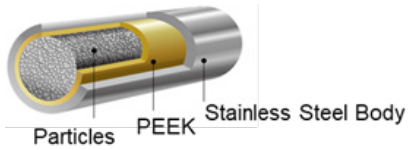
6. Shim-pack Scepter C18 Column Makes Amino Acid Analysis Effortless



Amino acids is the building blocks of proteins and is essential in cell culture media. Analysis of amino acids at various stages of the biopharma workflow enables quality and identification testing of biopharmaceuticals, process monitoring and also quantification of single or total amino acids in drugs. Derivatization is required for LC-UV and LC-Fluorescence detection of amino acids; There are various pre-column (e.g. PITC, OPA/FMOC, dansyl chloride) and post-column (ninhydrin) derivatization available. The analysis of amino acids can be made easier with Shim-pack Scepter C18 RP column, Nexera LC-40 and online pre-column derivatization.

6.1 Type of Column Used

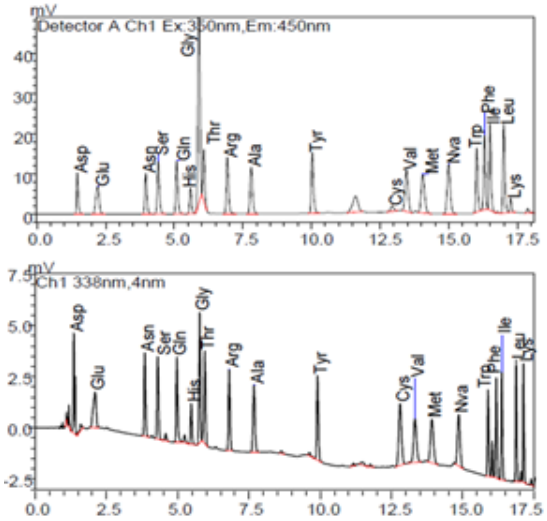
Shim-pack Scepter C18 Column



Shim-pack Scepter C18 column demonstrates high chemical stability in an expanded pH range, excellent peak shapes without adsorption, and peak tailing. Also, metal-free columns are available too.

Shim-pack Scepter C18	Excellent Stability and Performance
Bonded Phase	Trifunctional C18
Particle Size	1.9 µm, 3 µm, 5 µm Organic Silica Hybrid
Pore Size	120 Å
End-capped	Yes
pH Range	1 - 12
Maximum Temperature	90°C
USP Code	L1

6.2 Key Results and Chromatograms



Pre-column derivatization of 20 amino acids with OPA/FMOC followed by reversed phase separation on Shim-pack Scepter C18 column was conducted.

Application Feature

7. Shim-pack GIST Amide Column For High Separation in Glycan Analysis

Glycoprotein-based biotherapeutics and their biosimilars play an important role in the recombinant biopharmaceutical products today. Typically, any slight modifications at the glycosylation sites could greatly affect the stability, function, and immunogenicity of the proteins. To ensure the safety and efficacy of the drug, glycan variants analysis is essential though it could be difficult due to the inherent complexity and heterogeneity of protein glycosylation. This challenge can be solved with Shim-pack GIST Amide column – with its unique selectivity and ability to strongly retain polar compounds, it can provide high-resolution separation for oligosaccharides and glycans even with similar structures.

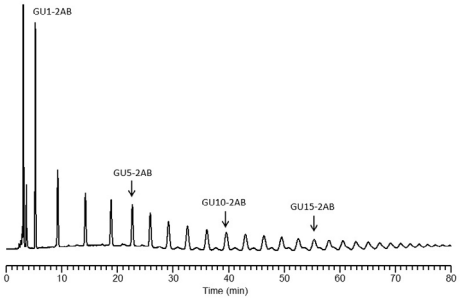
7.1 Type of Column Used

Shim-pack GIST Amide

Bonded Phase	Amide (Carbamoyl) Groups
Particle Size	1.9 µm, 3 µm, 5 µm
Pore Size	10 nm
Surface Area	350 m²/g
Carbon Loading	15%
End-capping	No
pH Range	2 to 8.5
USP Code	L68

7.2 Key Results and Chromatograms

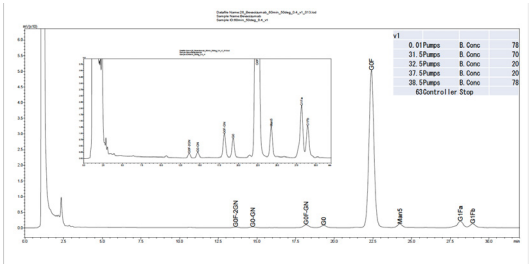
7.2.1 Analysis of Oligosaccharides Derivatized With 2-AB



Column	Shim-pack GIST Amide (5 µm, 250 x 4.6 mm I.D.) (P/N: 227-30827-07)
Mobile Phase	Acetonitrile B) 50 mM Ammonium formate (pH 4.4, formic acid) A/B = 80/20 – 20 min – 65/35 – 60 min – 50/50 – 10 min – 50/50 (v/v)
Flow Rate	1 mL/min
Col. Temp.	50°C
Detection	RI
Inj. Vol.	25 µL
Samples	2-AB Labeled Glucose Homopolymer Ladder

HILIC separation of 2-AB Labeled Glucose Homopolymer Ladder using Shim-pack GIST Amide Column was conducted. Excellent separation with good, narrow peak shapes were achieved.

7.2.2 Determination of mAb glycosylation with S-Bio Kit



This shows the chromatogram of labeled N-glycans from bevacizumab biosimilar. N-glycan profiles were well-separated, especially the isomers G1Fa and G1Fb. Therefore, accurate quantitation of target glycans can be performed.

LC Conditions	
LC System	Shimadzu Nexera UHPLC
Column	Shim-pack GIST Amide (150 mmL. x 2.1mmI.D., 1.9 µm) P/N: 227-30947-05
Col. Temp.	50°C
Flow Rate	0.4 mL/min
Mobile Phase A	50 mmol/L ammonium formate
Mobile Phase B	Acetonitrile
Gradient Program	B.Conc. 75% (0 min) → 70% (31.5 min) → 20% (32.5-37.5 min) → 78% (38.5 min)
Inj. Vol.	5 µL
Fluorescence Conditions	
Detector	Fluorescence Detector RF-20A
Excitation Wavelength	330 nm
Emission Wavelength	420 nm
Gain	1

Resources

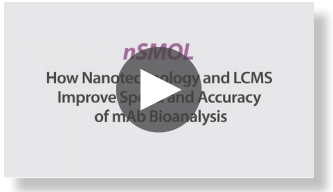
Compilation of Biopharma Resources

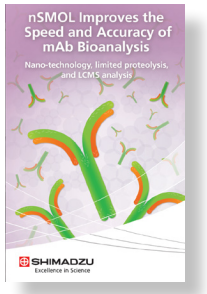
Webinars

Videos

How Nanotechnology & LC-MS Improve Speed & Accuracy of mAb Bioanalysis

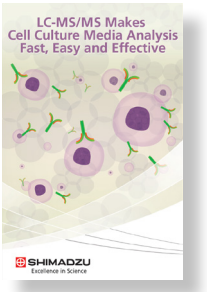
Related Application Book:





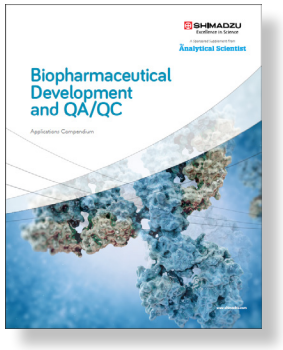
Advanced Cell Culture Media Analysis and Monitoring by LC-MS/MS

Related Application Book:

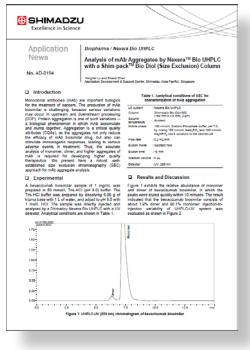


All about Biopharmaceuticals: Accelerating your Workflows with Shimadzu

Applications

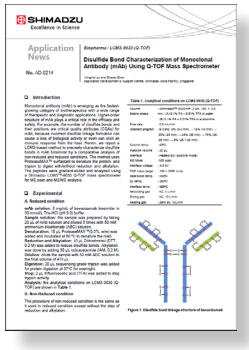


Biopharmaceutical Applications Compendium

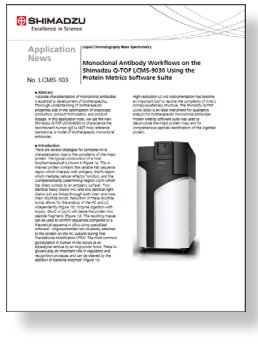


Analysis of mAb Aggregates by Nexera Bio UHPLC with a Shim-pack Bio Diol (Size Exclusion) Column

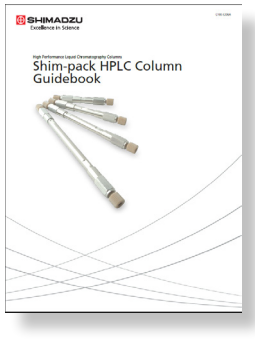
Peptide Mapping of mAb using LCMS-9030 Q-TOF MS with a Shim-pack GISS-HP Column



Disulfide Bond Characterization of mAb using Q-TOF MS



mAb Workflows on the Shimadzu Q-TOF LCMS-9030 using the Protein Metrics Software Suite



Shimadzu HPLC Column Guidebook

Resources

Shimadzu Total Solution for Biopharmaceuticals

1. Chromatography

With high stability, precision, and efficiency, equipped with smart features and automation capabilities, Shimadzu LC systems prove to meet all needs and requirements for your biopharma applications.

2. Spectroscopy

A variety of spectroscopy techniques and detectors (UV-Vis, Fluorescence, and Molecular Spectroscopy) available for coupling with liquid chromatography (LC) to cater to all your biopharma analysis.

3. Mass Spectrometry

With our outstanding capabilities in MS, Shimadzu developed the Ultra-Fast Mass Spectrometry (UFMS) and High-Resolution Accurate-Mass (HRAM) Q-TOF MS for your quantitative and qualitative analysis.

4. Life Sciences

Instruments and techniques such as MALDI-TOF MS, aggregate sizer, automated protein separation, and protein sequencer are developed to help accelerate biopharma research and meet the needsof all biopharma applications.

5. Columns & Consumables

A full range of laboratory consumables, columns, and vials are available to support all your analysis. Shim-pack columns are developed to provide excellent, accurate, and stable separation.

6. Informatics (Data Analysis / Data Integrity / Regulatory Compliance)

Shimadzu informatics system and LabSolutions analysis data software features an innovative operating environment and provide complete data management to ensure secure information and regulatory compliance in networked laboratories.

7. Solutions (Cell Culture Media Analysis / nSMOL Antibody BA Kit)

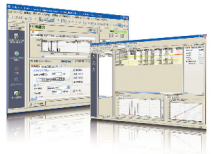
With our promise in innovation, Shimadzu constantly develops new solutions and methods to simplify your biopharma workflow and achieve high productivity and accurate results.

MALDI

MALDI-8020

- Glycopeptide Analysis of mAB's Structural Analysis

Informatics



Labsolutions DB/CS

- Regulatory Compliance CFR21 Compliance

LC Platforms

Nexera Series System

Prominence Inert LC System

- Protein Sequence Amino Acid Analysis
- Glycan Analysis Aggregate SEC

LC-MS/MS

LCMS-9030 LCMS-8060

- nSMOL Cell Culture Profiling mAB Quantitation

ICP-MS

ICPMS-2030

- Elemental Impurities in Pharmaceutical Products

Spectro

UV / Fluorescence

- Spatial Structure of Antibodies Impurity Detection

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Shimadzu (Asia Pacific) Pte Ltd: September, 2021

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