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WELCH MATERIALS, INC.

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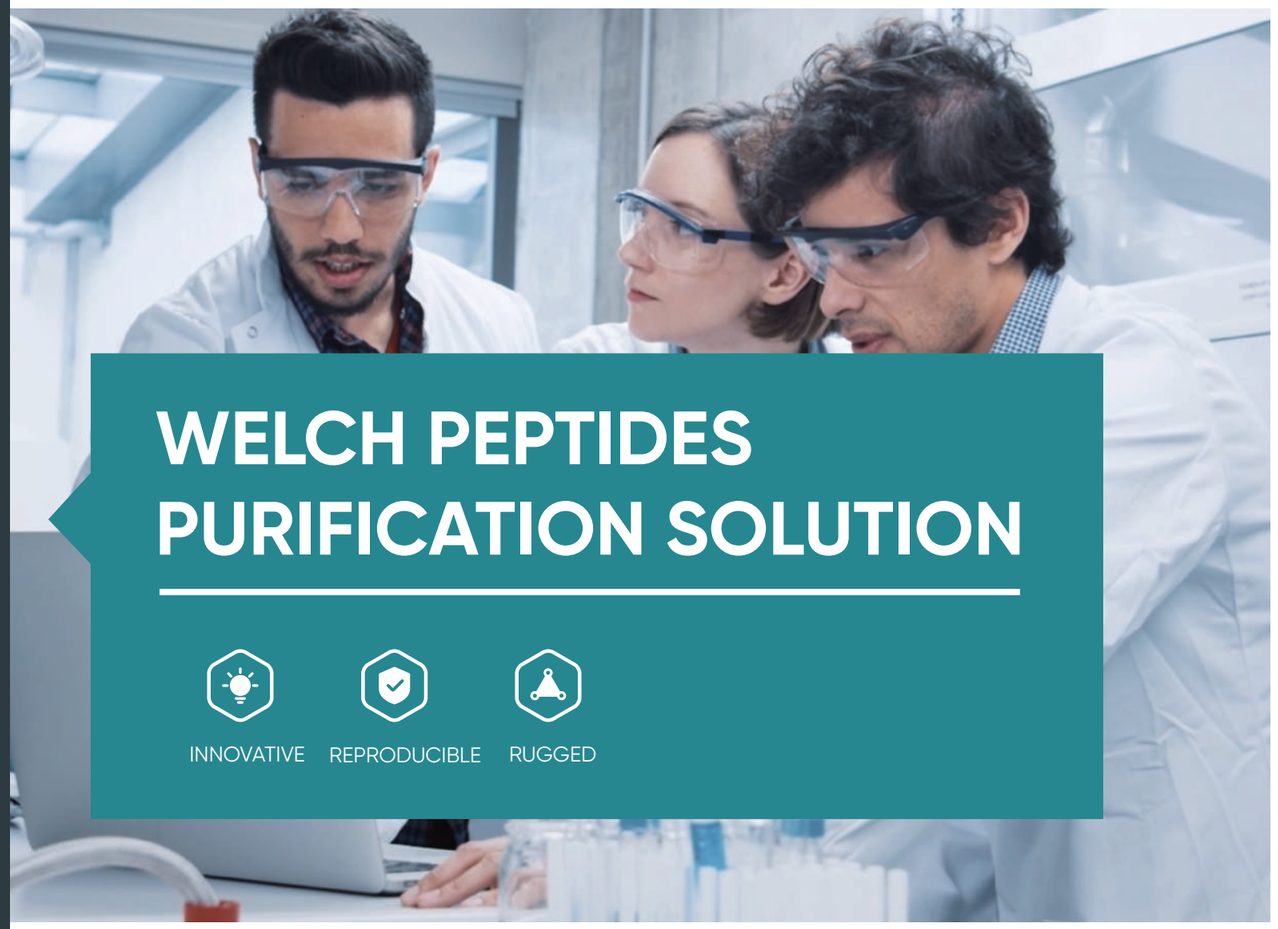
Welch Materials



WELCH PEPTIDES PURIFICATION SOLUTION

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WELCH MATERIALS, INC.

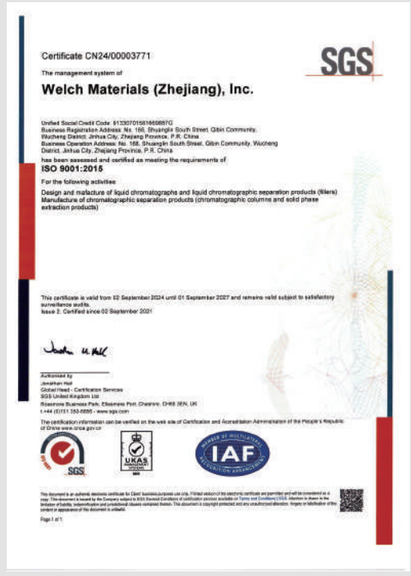
COMPANY PROFILE

Welch Materials is a multinational company specializing in the development and manufacturing of laboratory products. Our extensive range of offerings includes HPLC columns, GC columns, chromatographic packing materials, sample preparation products, protein purification products, laboratory instruments, and general consumables.

Established in August 2003, Welch Materials, Inc. has its headquarters in Songjiang, Shanghai. In addition to our main office, we operate production and research facilities in Jinhua, Zhejiang, and Nanjing, Jiangsu. Furthermore, we have established subsidiary branches in the United States, India, and Canada.

At Welch Materials, Inc., we seamlessly integrate research, production, sales, and service to provide comprehensive laboratory solutions worldwide. Our products have wide-ranging applications in vital industries such as biomedicine, food safety testing, environmental monitoring, and fine chemicals, making a significant contribution to improving people's lives.

In 2018, we proudly obtained the ISO 9001:2015 international quality management system certification, reaffirming our unwavering commitment to maintaining the highest quality standards. Through the implementation of rigorous quality inspection processes and strict adherence to standards, we ensure that each product we produce complies with the most stringent laboratory requirements.


Certificate CN24/00003771

SGS

The management system of

Welch Materials (Zhejiang), Inc.

Unified Social Credit Code: 91330701581696881G
Business Registration Address: No. 166, Shuangbi South Street, Gibin Community, Wucheng District, Jinhua City, Zhejiang Province, P.R. China
Business Operation Address: No. 166, Shuangbi South Street, Gibin Community, Wucheng District, Jinhua City, Zhejiang Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design and mafacture of liquid chromatographs and liquid chromatographic separation products (fillers)
Manufacture of chromatographic separation products (chromatographic columns and solid phase extraction products)

This certificate is valid from 02 September 2024 until 01 September 2027 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 02 September 2021

Authorised by
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CONTENT

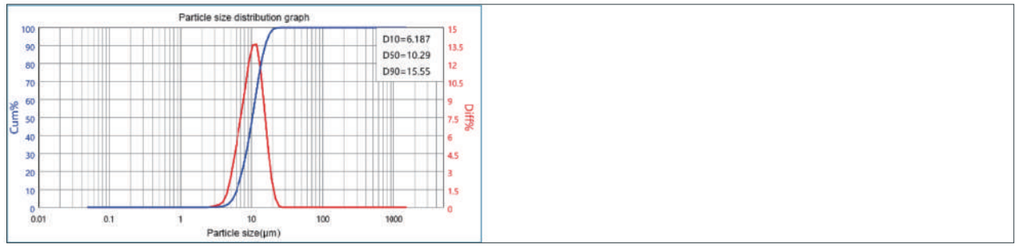
01 OVERVIEW

Ultra-High Purity Spherical Silica Gel

Welch utilizes advanced pelletizing technology to manufacture ultra-high purity spherical silica gel packing materials, ensuring precise control over particle size and pore size distribution. This results in superior product performance and outstanding separation efficiency.

Benefits of Ultra-High Purity Spherical Silica Gel:

- **Stable column bed:** Delivers high column efficiency.
- **Uniform particle size:** Reduces column pressure and increases flow rate.
- **Improved hydrodynamic distribution:** Promotes even diffusion in both horizontal and vertical directions, leading to symmetrical peak shapes.
- **Ultra-high purity:** Minimizes impurity interference.

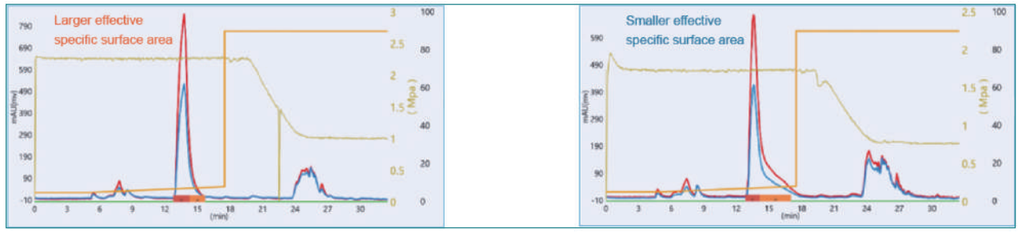


Larger Effective Specific Surface Area

The pore size distribution significantly impacts the specific surface area of silica gel packing materials. A narrower pore size distribution increases the number of effective pores available for the target compound, resulting in a higher effective specific surface area and facilitating separation and purification.

Benefits of narrower pore size distribution:

- Increased effective specific surface area.
- Improved recovery.
- Higher sample loading capacity.
- Reduced peak tailing.
- Minimized irreversible adsorption.
- Reduced operational costs.

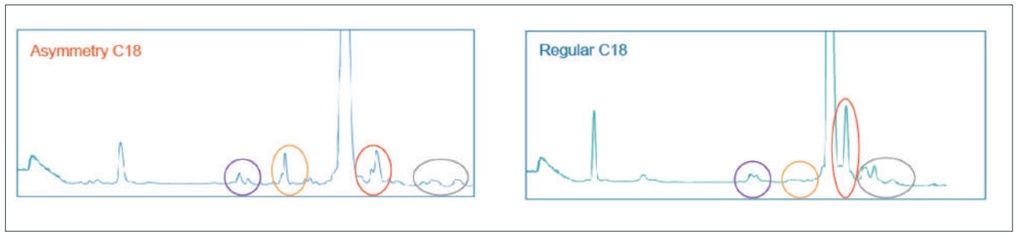


Unique Bonding Process for Enhanced Separation

Welch's proprietary asymmetric bonding technology optimizes separation efficiency by leveraging entropy-driven differentiation of target compounds from impurities.

Benefits of Enhanced Chemical Stability:

- Enhanced separation of target compounds.
- Increased sample loading capacity.
- Improved product recovery.
- Reduced operational costs.



Excellent Chemical Stability

Welch employs surface hybridization technology to achieve high surface density of bonded phases, ensuring superior protection of the silica gel matrix. This innovation enables stability across a broad pH range.

Benefits of Enhanced Chemical Stability:

- Compatibility with a wider range of mobile phases.
- Optimized sample loading conditions.
- Improved column regeneration performance.
- Extended column lifespan.

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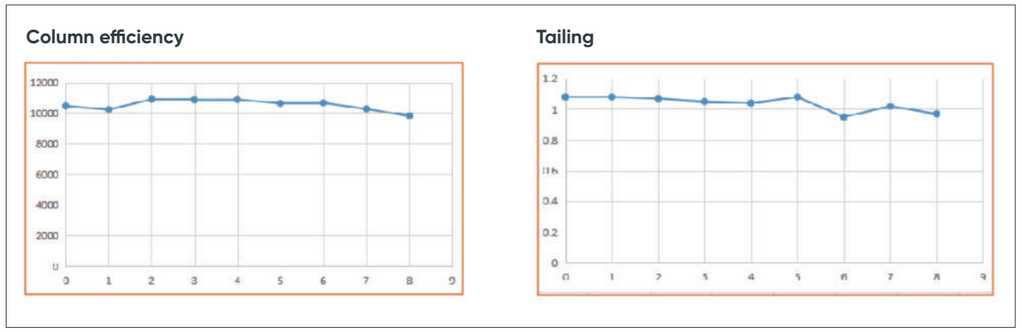


Seamless Scale-Up from Laboratory to Industrial Production

Welch offers a comprehensive range of silica gel chromatographic packing materials, featuring diverse particle sizes, pore sizes, and bonded phases to accommodate a variety of separation needs. Additionally, Welch provides chromatographic columns in multiple specifications, supporting seamless transition from laboratory-scale research to industrial-scale production. Customers benefit from a one-stop solution for all chromatography needs, ensuring an efficient and streamlined production process.

R&D:

Analytical HPLC columns, flash columns, and other consumables

Process:

Multi-size packing materials for preparative chromatography

Production:

Large-scale packing materials for industrial preparative chromatography

Optimized Performance Through Multi-Matrix, Multi-Specification, and Multi-Bonded Phase Combinations

	Small molecules	Polypeptides	GLP-1	Oligonucleotide drugs	Synthetic compounds	Natural compounds
Ultisil CHS	✓	✓	✓		✓	✓
Ultisil BHS	✓	✓	✓	✓	✓	✓

02 PACKING MATERIALS

Ultisil CHS Series

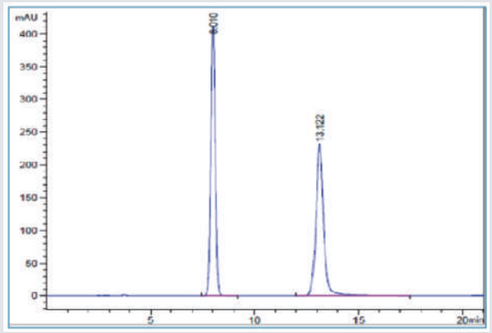
The Ultisil CHS series is a premium silica gel chromatographic packing material. Its advanced sphere packing technique and precise control over particle size and pore size distribution ensure a larger effective specific surface area, minimal peak tailing, higher sample loading capacity, superior stability under high pH conditions, and enhanced mechanical strength. It is particularly suitable for the purification of polypeptide products, especially insulin and GLP-1 (including its analogues).

Features and Advantages of Ultisil CHS Series:

- Uniform particle size: Low column pressure and high column efficiency.
- Superior bonding technology: Greater tolerance to high pH conditions.
- Larger effective specific surface area: Reduced tailing and dead adsorption, leading to higher efficiency.
- High-purity silica gel: Total metal content ≤20 ppm.

Low metal residue

Metal interactions on the silica gel surface can alter the selectivity of chelates and affect peak shapes. Variations in the capacity factor and tailing factor of 2,3-dihydroxynaphthalene (a chelating compound) serve as indicators of secondary interactions caused by metal impurities in the silica gel.



Chromatograhic Conditions:
Packing Material: Ultisil CHS C18 (10 μm, 100 Å)
Mobile Phase: H2O:CH3OH = 50%:50%
Sample: 1. 2, 7-dihydroxynaphthalene, 2. 2, 3-dihydroxynaphthalene
Detector: UV, 254 nm
Flow Rate: 0.8 mL/min
Detector Temperature: 30°C

Highly Deactivated Surface

When pH exceeds 7, dissociated silanol groups can degrade peak shapes in protonated basic compounds such as amitriptyline. Secondary ion exchange and silanol interactions contribute to retention drift and asymmetric peaks. The capacity factor and tailing factor of amitriptyline serve as key indicators of the overall column performance.

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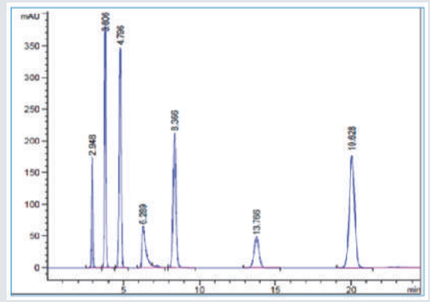


Chromatographic Conditions:
Packing Material: Ultisil CHS C18 (10 μm, 100 Å)
Mobile Phase: 10mM K2HPO4:CH3OH=20%:80%
Samples: 1. Uracil, 2. Dimethyl phthalate, 3. Butylparaben,
4. Propranolol, 5. Naphthalene, 6. Acenaphthene, 7. Amitriptyline
Detector: UV, 254 nm
Flow Rate: 1.0 mL/min
Detector Temperature: 30°C

Product Specifications

	Bonded Phase	Particle Size (μm)	Pore Size (Å)	Max Pressure (MPa)	SSA (m^2/g)	Carbon Load	pH
Ultisil CHS C8	C8	10	100	40	320	12%	2-9
Ultisil CHS C8 Pro	C8	10	100	40	320	10%	2-10

Ordering Information

	Particle Size (μm)	Pore Size (Å)	P/N
Ultisil CHS C8	10	100	H02756-03600
Ultisil CHS C8 Pro	10	100	H02762-03600

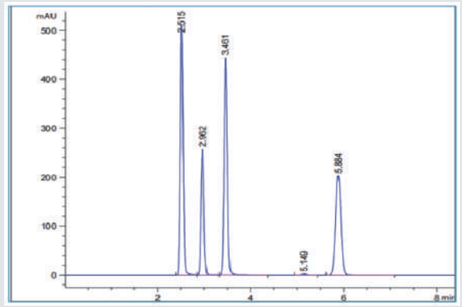
Ultisil BHS Series

The Ultisil BHS series is a high-purity silica gel chromatographic packing material designed for the purification of various small and medium-sized molecules. It is available in a wide range of particle sizes, pore sizes, and bonded phase options. In reversed-phase chromatography, Ultisil BHS delivers well-balanced performance in separation capacity, loading capacity, recovery, and mechanical strength.

Features and Advantages of Ultisil BHS Series:

- Uniform particle size: Low column pressure and high column efficiency.
- Larger specific surface area: Enhances sample loading capacity and improves separation efficiency.
- Superior bonding technology: Greater pH tolerance and compatibility with a wider range of mobile phases.
- Versatile Particle Size and Pore Size Combinations: Supports applications from analytical to preparative chromatography.

High Column Efficiency and Retention



Chromatographic Conditions:

Packing Material: Ultisil BHS C18 (10 μm, 120 Å)

Part No.: H02755-03100

Mobile phase: H2O:CH3OH=85%: 15%

Samples: 1. Uracil, 2. Nitrobenzene, 3. Phenol, 4. Naphthalene

Detector: UV, 254 nm

Flow rate: 1 mL/min

Product Specifications

	Bonded Phase	Particle Size (μm)	Pore Size (Å)	Max Pressure (MPa)	SSA (m^2/g)	Carbon Load	pH
Ultisil BHS C18	C18	10	100	40	450	19%	2-9
			120		320		
Ultisil BHS C18 Pro	C18	8	120	40	320	15%	2-10
Ultisil BHS C18 Plus	C18	10	120	40	320	17%	2-10
Ultisil BHS C8	C8	8	120	40	320	10%	2-9

Ordering Information

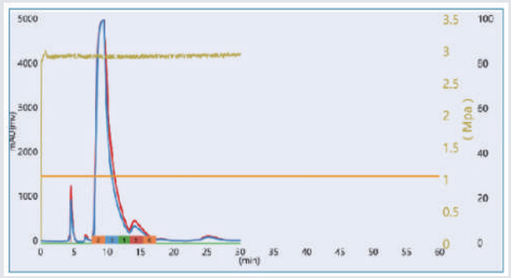
	Particle Size (μm)	Pore Size (Å)	P/N
Ultisil BHS C18	10	100	H02755-03600
		120	H02755-03100
Ultisil BHS C18 Pro	8	120	H02761-17100
Ultisil BHS C18 Plus	10	120	H02757-03100
Ultisil BHS C8	8	120	H02758-17100

03 APPLICATIONS

Applications

Insulin Separation

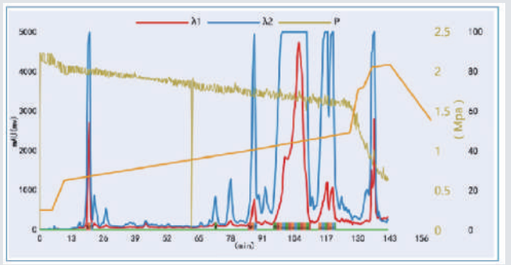
Insulin, a protein hormone, is secreted by beta cells in the islets of Langerhans in the pancreas in response to various endogenous or exogenous stimuli, such as glucose, lactose, nucleic acids, arginine, and glucagon. While insulin is the only hormone capable of lowering blood sugar levels and promoting the synthesis of glycogen, fat, and protein, its exogenous form is primarily utilized for diabetes treatment. Currently, insulin purification predominantly relies on reversed-phase chromatography, with Welch Ultisil CHS C8 (10 μm, 100 Å) packing material demonstrating exceptional efficacy in insulin separation.



Packing Material	Ultisil CHS C8 (10 μm, 100 Å)
Sample	Insulin
Loading Capacity	1%
Flow Rate	3 mL/min
Purity	99.60%
Recovery	88.50%

Antibiotic—Teicoplanin Separation

Teicoplanin, also known as Teichomycin, is a potent antibiotic used to treat Gram-positive bacterial infections caused by both anaerobic and aerobic bacteria. It is more effective than vancomycin and has fewer adverse reactions.



Packing Material	Ultisil BHS C18 (10 μm, 100 Å)
Sample	Teicoplanin
Loading Capacity	3%
Flow Rate	3 mL/min
Purity	99.50%
Recovery	80.02%

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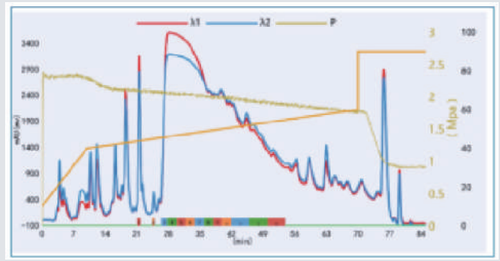
Chemical Synthesis of GLP-1 Liraglutide

Ultisil CHS C8 Pro is a high-performance silica gel chromatographic packing material specifically designed for the purification and production of chemically synthesized GLP-1. Built upon the strengths of the Ultisil CHS series, it features uniform particle size and an exceptionally high effective specific surface area. Additionally, its innovative bonding technology enhances separation efficiency, significantly improving product purity, recovery rates, and loading capacity.

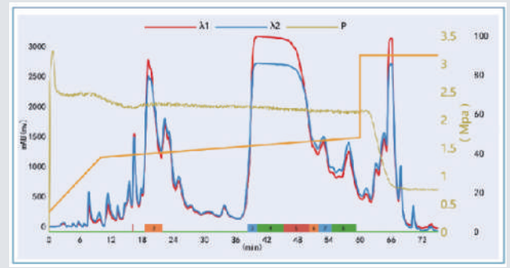


Packing Material	Ultisil CHS C8 Pro (10 μm, 100 Å)
Sample	Liraglutide
Loading Capacity	1%
Flow Rate	3 mL/min
Purity	99.77%
Recovery	74.79%

Chemical Synthesis of GLP-1 Tirzepatide

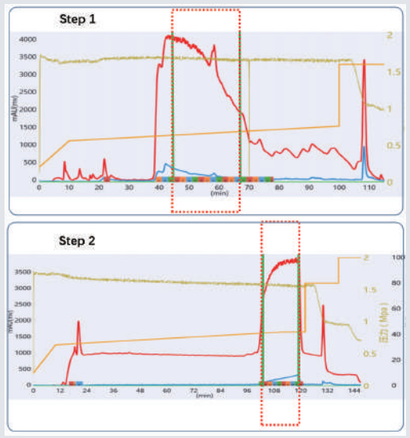
Tirzepatide is a novel dual agonist of the glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor, designed to bind to albumin and extend its half-life. Tirzepatide enhances both phase I and phase II insulin secretion while reducing glucagon levels in a glucose-dependent manner. It also lowers fasting and postprandial glucose concentrations, decreases food intake, and promotes weight loss in patients with type 2 diabetes mellitus.

Using Ultisil CHS C8 Pro



Packing Material	Ultisil CHS C8 Pro (10 μm, 100 Å)
Sample	Tirzepatide
Loading Capacity	1%
Flow Rate	3 mL/min
Purity	99.73%
Recovery	72.90%

Using Ultisil BHS C18 Plus

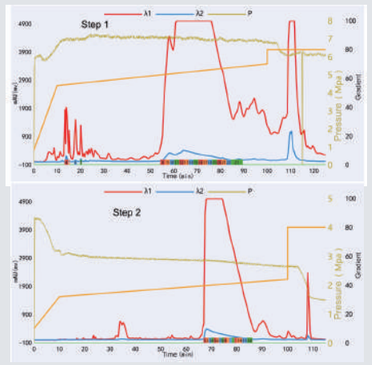


Packing Material	Ultisil BHS C18 Plus (8 μm, 120 Å)	
Sample	Tirzepatide	
Loading Capacity	1%	
Flow Rate	3 mL/min	
Purity	90.00%	99.11%
Recovery	74.89%	87.87%

Fermentation synthesis of GLP-1 Semaglutide

Semaglutide is an anti-diabetic medication used for the treatment of type 2 diabetes and an anti-obesity medication used for long-term weight management. It is a peptide similar to the hormone glucagon-like peptide-1 (GLP-1), modified with a side chain. Ultisil CHS C8 Pro and Ultisil BHS C18 Pro are designed for the purification of GLP-1 during fermentation synthesis. They effectively separate various biological impurities that arise during the synthesis process. With very high sample loading capacities and recovery rates, they ensure the purity of the final product while significantly enhancing production efficiency.

Using Ultisil CHS C8 Pro



Packing Material	Ultisil CHS C8 Pro (10 μm, 100 Å)	
Sample	Semaglutide	
Injection	240 mg	
Flow Rate	3 mL/min	
Purity	96.67%	99.86%
Recovery	75.68%	86.68%

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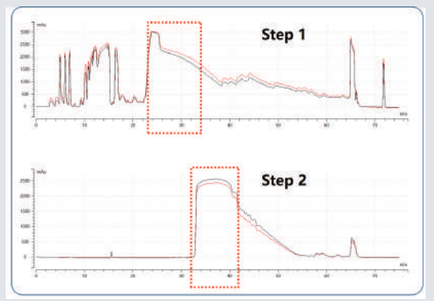
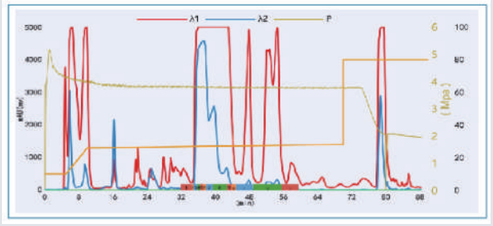
Using Ultisil BHS C18 Pro



Packing Material	Ultisil BHS C18 Pro (8 μm, 100 Å)	
Sample	Semaglutide	
Loading Capacity	2%	
Flow Rate	3 mL/min	
Purity	90.00%	99.81%
Recovery	93.00%	85.00%
Overall Recovery	79.05%	

Oligopeptides purification

Ultisil BHS C18 Pro is also a specialized silica gel packing material designed for the efficient separation of oligopeptides. By utilizing advanced bonding and anti-tailing technologies, it significantly improves separation efficiency and recovery rates.



Packing Material	Ultisil BHS C18 Pro (8 μm, 120 Å)
Sample	Oligopeptide-5
Loading Capacity	1%
Flow Rate	3 mL/min
Purity	99.00%
Recovery	90.02%

Relationship between Column Diameter, Silica Gel Packing Volume, and Recommended Flow Rate

Product Specifications

Column length: 250 mm					
Diameter (mm)	4.6	10	20	30	50
Packing volume (g)	3	18	60	120	350
Recommended Flow Rate (mL/min)	0.5-2	3-5	10-20	20-45	70-130

04 COMMON ISSUES AND SOLUTIONS

Common Issues and Solutions

Issues	Possible Causes	Solutions
High column pressure	Excessive flow rate	Reduce the flow rate.
	Residual sample or impurities	Clean the packing material.
	Sample precipitation	Adjust the buffer composition.
	Column bed collapse	Repack the column.
	Prolonged column usage	Replace the column or the packing material.
Baseline drift	Inadequate column equilibration	Extend the equilibration time
	Variation in eluent absorbance	Run a blank gradient.
	Contaminated eluent	Use high-purity HPLC-grade reagents
Low resolution	Unsuitable elution conditions (e.g., steep gradient or high flow rate)	Optimize elution conditions by using a shallower gradient or isocratic elution.
	Poor column packing	Evaluate column efficiency and repack if necessary.
	Broad peak dispersion at the column inlet or outlet	Increase the packing bed height or minimize dead volume at the column end.
	Column overload	Reduce sample load, clean the column, and re-equilibrate.
	Incomplete removal of sample or impurities after cleaning	Perform thorough column cleaning.
	Large particle size of the packing material	Replace with packing material of smaller particle size.
	Poor selectivity	Adjust or add ion-pair reagents, or use a different packing material.
	Mixed-mode retention due to silanol interactions	Lower the pH to suppress silanol activity or use a different column.
Early Elution of Sample (Before Gradient Elution)	High initial eluent concentration	Decrease the initial eluent concentration.
	Improper pH conditions	Adjust the pH to enhance sample binding
	Residual sample or impurities from repeated injections	Perform thorough column cleaning.

Common Issues and Solutions

Issues	Possible Causes	Solutions
Sample Not Eluted During Gradient Elution	Low final eluent concentration	Increase the final eluent concentration.
	Weak elution strength of the solvent	Use an eluent with higher elution strength.
	Sample precipitation due to pH changes	Adjust the pH to prevent precipitation.
Bubbles in the Column Bed	Mobile phase not properly degassed	Fully degas the buffer
	Bubble formation after mixing mobile phases	Use isocratic elution if feasible.
	Poor column packing	Repack the column
Ghost Peaks	Inadequate column cleaning	Use a stronger eluent to clean the column.
	Absorption from the eluent itself	Run a blank gradient as a control or switch to an eluent with no UV absorbance.
	Trace organic impurities binding to the column and being released during elution	Wash the column with a strong eluent to remove bound impurities.

05 DAC COLUMN PACKING GUIDE

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An Essential Guide to Efficiently Packing DAC Columns

Dynamic Axial Compression (DAC) columns are advanced preparative chromatography devices that integrate the functionality of column packing machines and chromatography columns. They utilize dynamic axial compression technology to pack, maintain pressure, and unpack columns, ensuring a uniform, tight, and stable column bed throughout use.
DAC technology is widely used for large-scale, high-efficiency separation and purification in laboratories and production facilities. It is particularly suitable for processes requiring reproducible and scalable purification solutions.

Structure of a DAC Column

A DAC column consists of several critical components:

Component	Function
Hydraulic Cylinder	Houses the hydraulic rod, allowing its vertical movement.
Oil Pressure Gauge	Displays the pressure within the cylinder.
Air Pressure Gauge	Indicates input air pressure.
Piston Switch	Controls the direction of piston movement.
Pressure Regulating Valve	Adjusts the pump output pressure.
Pneumatic Hydraulic Pump	Converts low air pressure to high hydraulic pressure using a large-area piston for air and a small-area piston for oil.
Safety Valve	Provides overpressure protection.
Oil Reservoir	Stores hydraulic oil.
Gas Filter	Filters incoming air to ensure a clean air supply.

Steps for Packing a High-Efficiency DAC Column

Step 1: Calculate Slurry and Packing Material Requirements

Column Volume:
$V = 3.14 \times r^2 \times L$
r: Internal radius of the column (cm)
L: Column length (cm)

Packing Material:
$m = \rho \times V$
ρ: Bulk density of the packing material (g/mL)
Due to compression, it is generally suggested to use ~1.1 times the calculated mass. The table below shows the required packing material mass to various specifications of WelPacker DAC when packing a 250 mm bed height.

Slurry Volume:
Typically, twice the packing material mass (e.g., 300 g of packing material requires ~600 mL slurry solvent). Isopropanol is a common slurry solvent.

DAC Specification (mm)	Recommended packing material mass (g)
50	302
100	1,209
150	2,720
200	4,836
300	10,880
450	24,480
500	30,223
600	43,520
800	77,370
1000	120,000

Example:

For a 50 mm DAC column with a 250 mm bed height, packing with 10 μm C18 material (bulk density: 0.56 g/mL) requires approximately 300 g of packing material and 600 mL of slurry solvent.

Step 2: Clean and Prepare Hardware

Proper cleaning ensures optimal performance:

- Column Tube: Remove oil and dust from the inner walls.
- Sieve Plates: Ultrasonically clean to remove clogs.
- Distributors and Seals: Wash to prevent contamination.
- Components: Dry thoroughly before assembly.
- Gas Source: Ensure suitability and stability before packing.

The WelPacker DAC employs H-tree distributors to ensure uniform fluid distribution, achieving symmetric chromatographic peaks.

Step 3: Prepare Slurry

Key considerations for slurry preparation:

• Use inert containers, filling up to 2/3 of their capacity.

• Mix using ultrasonic and mechanical stirring for ~30 minutes. (Ultrasonic not applicable to fragile materials)

• Ensure good fluidity of the slurry solvent and avoid being too viscous or too thin. The ideal state is that a uniform thin line would flow down if the glass rod was picked out of the slurry.

• For DACs of 300 mm or below, manual stirring can be applied; for above, a mixer is recommended.

• Avoid damaging fragile materials by limiting shear force and time.

Step 4: Assemble Column

WelPacker DAC50 Column Installation Demonstration [Video]

Step 5: Pack the Column

Key considerations for column packing:

• Clean all components (inner wall, piston, bottom cap, etc.) with isopropanol after pouring in the material. Ensure no residual contaminants.

• For persistent clogs, soak parts in 1 M sodium hydroxide for 12 hours, followed by thorough rinsing for 1 hour and ultrasonic cleaning for 3 ~ 6 times (10 ~ 15 minutes each). Ensure the final rinse has a neutral pH (~7).

• Adjust the air pressure to set value, vent air from the top, then press the slurry out from the bottom end. Once no more liquid is discharged from the bottom, the packing process is complete.

• Finally, allow the column to stabilize for 30 minutes, and then displace any remaining slurry solvent with methanol (or n-hexane).

Testing Column Efficiency

After packing, let the column equilibrate under pressure for 30 minutes before testing. Connect the column to the liquid chromatography system, using a recommended flow rate (e.g., 80 mL/min for a 50 mm column). Test column efficiency with 1 mL injections of naphthalene/methanol or toluene/methanol solutions (1 mg/mL).

Key Precautions During Packing

• Choose an appropriate solvent based on the packing material's properties.

• Use a suitable pneumatic hydraulic pump and adjust the pressure to ensure even compression across the column bed. For smaller columns, the bed should be compacted within 30 seconds to 1 minute.

• Allow the column to stabilize for 30 minutes after packing. or enhanced performance, flush the column with at least three column volumes of the mobile phase to replace the slurry solvent before testing, minimizing irregularities during the initial runs.

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Maintenance and Care

• **Post-Use Cleaning:** Flush the column immediately after use. For salt-based buffers, start with a rinse using a high-water-content solvent, followed by a high-organic solvent to clear residues. Reverse flushing, if compatible with the column design, effectively clears blocked particles.

• **Hydraulic Oil:** Regularly check the hydraulic oil condition. Refill or replace the oil as necessary to maintain optimal pressure levels and prevent system wear.

• **Component Inspection:** Perform routine inspections every six months. Check key components such as filter screens, seals, and the hydraulic system. Replace worn or damaged parts promptly to avoid performance degradation and ensure safe operation. Pay attention to signs of corrosion or residue buildup on seals and connectors.

Packing Material Storage

• **Unused packing material**

Store the packing material in its original container and keep it in a cool, dry environment, avoiding exposure to high temperatures and humidity.

• **Used packing material**

After the preparative process is completed, clean the column following the appropriate cleaning procedure: First, wash off any residual buffer salts with a low-concentration organic phase aqueous system (acetonitrile/water is recommended). Then, flush the column with a high-concentration organic phase.

After cleaning, the packing material can be stored either wet or dry in the column. For wet storage, use an anhydrous and neutral organic solvent. For dry storage, replace the packing material with an organic solvent such as acetonitrile, then remove the packing material from the column, dry it in an oven at a temperature not exceeding 90°C, and store it in a sealed container at room temperature.