ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ PHARMPREP P

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PharmPrep™ P Sorbent

High-Performance Spherical Chromatography Sorbent

PharmPrep™ P Sorbent is the latest development in our silica sorbent range. The particles have a spherical shape and are available in two particle sizes: 10 and 20 µm. Together with a pore diameter of 100 Å (10 nm), these new sorbents fit perfectly into the polishing step of peptides, like insulin as well as other biopharmaceuticals and pharmaceutical APIs, like antibiotics and hormones.

This highly porous silica is produced by spray drying. Because we perform the entire manufacturing process, you benefit from consistent batch-to-batch purification, while ensuring superior quality standards and regulatory compliance.

Preparative Liquid Chromatography

PharmPrep™ P sorbent for preparative liquid chromatography (LC) is a spherical, porous silica sorbent characterized by:

- Uniform and homogenous silica gel matrix with excellent batch-to-batch reproducibility
- Narrow particle size distribution for high performance and high packing stability
- Reproducible specific surface area and pore size distribution
- Enhanced mechanical stability
- General high-manufacturing quality and reproducibility
- Low back pressure

Benefits

- High productivity in peptide purification processes
- Superior loading capacity and selectivity
- High specific surface area
- Outstanding reproducible purification processes over many column packings
- Long lifetime due to high mechanical stability
- Excellent chemical stability

Polishing of Insulin

As seen in Figure 1, PharmPrep™ P sorbents demonstrate a perfect separation of insulin and the main impurities, e.g. des-amido insulin.

With this polishing step using PharmPrep™ P sorbent, a final outstanding insulin purity of 99.8% can be achieved. Typical load is 8 g crude Insulin per L Column volume which is equivalent to 15 g per kg stationary phase.

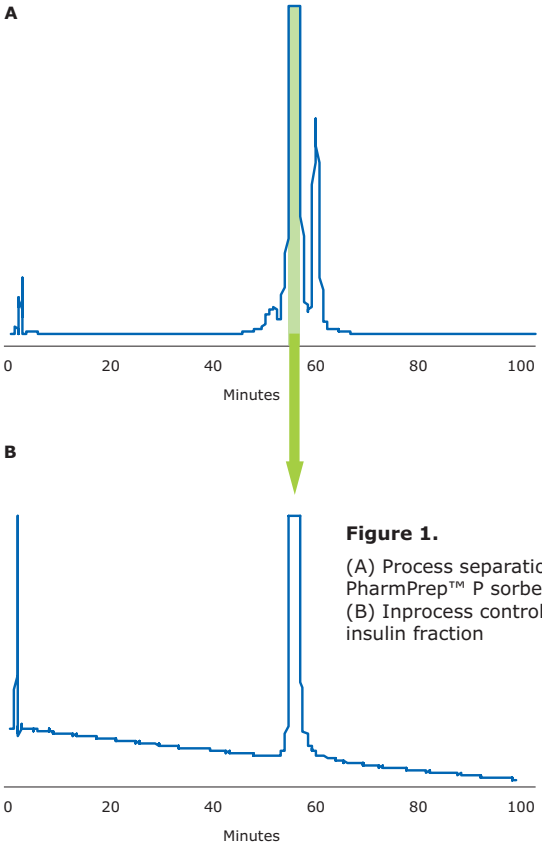

Figure 1.

(A) Process separation on PharmPrep™ P sorbent
(B) Inprocess control of insulin fraction

PharmPrep™ P 100 RP-18e, 10 µm sorbent chromatographic conditions for polishing of crude human insulin (90% pure)

Specifications	
Column size	250 x 4.6 mm
Mobile phase	A: 0.1 M $(NH_4)H_2PO_4$ pH 7.3
	B: 0.1 M $(NH_4)H_2PO_4$ pH 7.3 /ACN 50/50 (v/v) (Gradient mode 65% A to 30% A in 100 min)
Flow rate	1.325 mL/min
Temp.	25°C
Detection	UV 214 nm
Injection volume	100 µL
Sample	18 mg/mL crude human insulin rec. dissolved in water + 0.1% TFA

PharmPrep™ P 100 RP-18e and RP-8e, 10 µm Sorbent

- High selectivity
- High loadability

…and an insulin purity of 99.8%

- High flow rate
- High throughput

High Selectivity

Controlling the physical and chemical properties of stationary phases is important, but only a comprehensive chromatographic characterization ensures a consistently high level of reproducibility. To characterize selectivity, different approaches have been applied by leading high performance liquid chromatography (HPLC) scientists.

The “Tanaka Test” is established worldwide as an industrial standard test that assesses selectivity and performance differences between HPLC columns. These column parameters are known for effectively choosing the appropriate HPLC column for a specific separation, and enables easy comparison of columns.

A set of seven selected substances is used to describe capacity, hydrophobicity, steric selectivity and silanophilic properties. To recognize the quality of a sorbent easily, the values of these parameters are outlined on the six axes of a hexagon. The more symmetrical the hexagon is and the larger its area, the more balanced the stationary phase is in the sum of its chromatographic properties.

Production

The Gernsheim plant, based in Germany, where PharmPrep™ P silica is produced, complies with DIN ISO 9001 and DIN ISO 14001, and several GMP-related measures have been implemented.

- Reliable, well-controlled production processes
- More than 100 years of chromatography know-how
- We are the largest dedicated producer of chromatographic silica gels in the world
- Large batch sizes
- Custom packaging sizes to meet your requirements — from a single source, ranging from grams to tons
- Merck silica packing materials are designed to meet the highest demands in HPLC, SFC and SMB, from analytical to process scale.

Physical and Chemical Data

Parameter	Range		Typical Value		Method
PharmPrep™ P Si100 sorbent					
Particle Size Distribution	10 µm d_{50}	10–13 µm	d_{50}	10 µm	Particle size distribution
	20 µm d_{50}	15–20 µm	d_{50}	18 µm	
	d_{90}/d_{10}	≤2.5	d_{90}/d_{10}	≤2.5	
Specific Surface Area	320 – 400 m^2/g		370 m^2/g		Nitrogen sorption of basic silica gel (BET)
Specific Pore Volume	0.8 – 0.9 mL/g		0.8 mL/g		
Mean Pore Size	10 nm		10 nm (100 Å)		
Metal Ion Content	Na ≤25 µg/g		Na ≤2 µg/g		ICP-MS
	Al ≤50 µg/g		Al ≤20 µg/g		
	Fe ≤25 µg/g		Fe ≤2 µg/g		
Efficiency	≥18000 (N/m) (10 µm)		25000 (N/m)		2-nitro toluene, n-heptane/1.4-dioxane 99/1 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm columns
Pressure	≤25 bar (10 µm)		10 bar		n-heptane/1, 4-dioxane 99/1 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm column
	≤10 bar (20 µm)		4 bar		
PharmPrep™ P 100 RP-18e sorbent					
Carbon	17% – 21%		20%		Elemental analysis
Efficiency	≥20000 (N/m) (10 µm)		30000 (N/m)		Toluene, acetonitrile/water 75/25 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm columns
Pressure	≤40 bar (10 µm)		10 bar		Acetonitril/water 75/25 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm columns
	≤25 bar (20 µm)				
Selectivity alpha (Phenol/Pyridine)	≥1.8 – ≤3.0		2.5		Acetonitrile/water 70/30 (v/v), flow rate: 1.3 mL/min
Capacity factor (3-Nitro Acetanilide)	2.9 – 3.9		3.4		Acetonitrile/water 70/30 (v/v), flow rate: 1.3 mL/min
PharmPrep™ P 100 RP-8e sorbent					
Carbon	11% – 14%		13%		Elemental analysis
Efficiency	≥20000 (N/m) (10 µm)		30000 (N/m)		Toluene, acetonitrile/water 75/25 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm columns
Pressure	≤40 bar (10 µm)		25 bar		Acetonitril/water 75/25 (v/v), flow rate: 1.3 mL/min, 250 x 4.6 mm columns

Ordering Information

Description	Catalogue No.
PharmPrep™ P Si100, 10 µm silica sorbent	**119681**
PharmPrep™ P Si100, 20 µm silica sorbent	**119682**
PharmPrep™ P 100 RP-8e, 10 µm silica sorbent	**119132**
PharmPrep™ P 100 RP-18e, 10 µm silica sorbent	**119995**
PharmPrep™ P 100 RP-18e, 20 µm silica sorbent	**119996**
Ready-to-use HPLC columns	
Scout column 250 x 4.6 mm PharmPrep™ P 100 RP-8e, 10 µm silica sorbent	**120594**
Scout column 250 x 4.6 mm PharmPrep™ P 100 RP-18e, 10 µm silica sorbent	**120571**
Scout column 250 x 4.6 mm PharmPrep™ P 100 RP-18e, 20 µm silica sorbent	**120572**
HIBAR® pre-packed columns 250 x 25 mm PharmPrep™ P RP-8e, 10 µm silica sorbent	**120588**
HIBAR® pre-packed columns 250 x 25 mm PharmPrep™ P 100 RP-18e, 10 µm silica sorbent	**120573**
HIBAR® pre-packed columns 250 x 25 mm PharmPrep™ P 100 RP-18e, 20 µm silica sorbent	**120574**
HIBAR® pre-packed columns 250 x 50 mm	On request

HIBAR® and scout pre-packed columns are manufactured under strictly controlled conditions to ensure both excellent results and reproducibility. Each packed column is provided with a Certificate of Analysis.

Validation kits	
3 x 100 g packages of 3 different lots PharmPrep™ P 100 RP-8e, 10 µm silica sorbent	**1.19132.0003**
PharmPrep™ P 100 RP-8e, 10 µm silica sorbent	**1.19681.0003**
PharmPrep™ P 100 RP-18e, 20 µm silica sorbent	**1.19682.0003**

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