

1.20571.0001

1.20572.0001

Scout column 250 x 4.6 mm

PharmPrep® P100

1.20571.0001 PharmPrep® P100 RP-18e, 10 µm

1.20572.0001 PharmPrep® P100 RP-18e, 20 µm

1. INTRODUCTION

PharmPrep® P is the latest development in our silica sorbent range.

The particles have a perfect spherical shape and are available in two particle sizes: 10 and 20 µm. Together with a pore dia meter of 100 Å (10 nm) our new sorbents are perfect fitting into the polishing step of small peptides like insulin and other biopharmaceutical and pharmaceutical APIs.

This highly porous silica is produced by spray drying in our modern Silica production facility in Gernsheim, Germany which is one of the biggest in the world.

The fact that we perform the entire process ourselves gives our customers the advantage of consistent purification from batch to batch while ensuring superior quality standards and regulatory compliance.

PharmPrep® P sorbent for preparative liquid chromatography (LC) is a spherical, porous silica carrier 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

PharmPrep® P100 RP-18e scout columns are designed for the rapid evaluation of PharmPrep® P100 RP-18e resins for process development. The results obtained for separations using these scout columns are generally comparable to the results achieved using bigger scale columns (e.g. 250 x 25 mm i.d.).

Thus, in process design, the scout columns can be used to rapidly determine if a target molecule can be separated. In addition, data from experiments using PharmPrep® P100 RP-18e scout columns allow one to determine whether an appropriate target yield may be achieved and whether major contaminants could potentially be removed. After choosing PharmPrep® P100 RP-18e resin, bulk resin is available for preparative work on larger scale.

• General Characteristics of PharmPrep® P100 RP-18e

Parameter	Range	Typical Value
Particle size distribution	10 µm d_{50} 10 - 13 µm 20 µm d_{50} 15 - 20 µm	d_{50} 10 µm d_{50} 18 µm d_{90}/d_{10} ≤ 2.5 µm
Specific surface area	320 - 400 m ² /g	370 m ² /g
Specific pore volumen	0.8 ml/g	0.8 ml/g
Mean pore size	10 nm (100 Å)	10 nm
Carbon	17 - 21%	20%
Metal ion content	Na ≤ 25 µg/g Al ≤ 50 µg/g Fe ≤ 25 µg/g	Na ≤ 2 µg/g Al ≤ 20 µg/g Fe ≤ 2 µg/g
Efficiency	≥ 20000 (N/m) (10 µm)	30000 (N/m)
Pressure	≤ 40 bar (10 µm)	25 bar
Selectivity α		
(Phenol/Pyridine)	≥ 1.8 - ≤ 3.0	2.5
Capacity factor		
(3-Nitro acetanilide)	2.9 - 3.9	3.4

2. GUIDELINES FOR USE OF PHARMPREP® P100 RP-18E

• Equilibrating the column

PharmPrep® P100 RP-18e columns are shipped in acetonitrile/water. Verify that your mobile phase is miscible with the shipping solvent. As it can dry during stocking and shipping thoroughly activate the packing by purging 10 - 20 column volumes of pure organic component before equilibrating the column with the mobile phase.

To equilibrate the column: Gradually increase the flow rate in small increments from 0 ml/min to your conditions. Flush the column with your mobile phase until you get a stable baseline. Low concentrated mobile phase additives (ion pair reagents) may need longer equilibration (10 column volumes).

• Regeneration of reversed phase silica columns

For regeneration of reverse phase silica gel, back flush the column with the different solvents recommended in the table below. The flushing volume for complete regeneration amounts to approximately 20 column volumes CV.

The first step in the washing procedure for a reverse phase silica gel is to clean it with water, to remove all buffer.

Otherwise the salt of the buffer could precipitate out of solution plug the stationary phase.

Solvent	CV
Methanol/Water 50/50	4
Distilled water (up to 55°C)	2
Acetonitrile	2
2-Propanol	2
Heptane	4
2-Propanol	2
Acetonitrile	3
Mobile phase without buffer	1

• Regeneration Instruction for Protein Removal

Solvent	CV
Distilled water	2
0,1% TFA in water	7
2-Propanol	3
Acetonitrile	4
Distilled water	3
Mobile phase	1

• Storage

Prior to storing wash the column following a regeneration method written above but stop the procedure after the last Acetonitrile washing step.

3. Ordering Information

PharmPrep® P100 RP-18e, 10 µm	1.19995
PharmPrep® P100 RP-18e, 20 µm	1.19996
PharmPrep® P Si100, 10 µm	1.19681
PharmPrep® P Si100, 20 µm	1.19682
Scout column 250 x 4.6 mm	
PharmPrep® P100 RP-18e, 10 µm	1.20571
Scout column 250 x 4.6 mm	
PharmPrep® P100 RP-18e, 20 µm	1.20572

Ready-to-use HPLC columns are available

Hibar® pre-packed 250 x 25 mm	
PharmPrep® P100 RP-18e, 10 µm	1.20573
Hibar® pre-packed 250 x 25 mm	
PharmPrep® P100 RP-18e, 10 µm	1.20574
Hibar® pre-packed 250 x 50 mm	on request

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Made in Germany

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