HiScreen MabSelect

Product Information

Cat#No#	Hi-007P

Product Overview

HiScreen MabSelect is prepacked with MabSelect and is part of the process development platform available from Cytiva. The columns are an excellent choice for method optimization and parameter screening for capture of monoclonal antibodies (MAbs).

Description

The small column volume of 4.7 mL and bed height of 10 cm make HiScreen columns excellent tools for method optimization, parameter screening, robustness testing, and convenient scale-up. Process fluid velocities can be applied, since the 10 cm bed height gives enough residence time and the results can then serve as basis for linear process scale-up.

Characteristic

MabSelect is a BioProcess resin for capture of MAbs from large sample volumes.
Prepacked, ready-to-use columns for convenient process development.
10 cm bed height of HiScreen columns is designed to allow method optimization and parameter screening.
Easily connected in series to achieve 20 cm bed height.
Small bed volume gives fast results and minimal sample/buffer consumption.
Reproducible results, scalable to BioProcess columns packed with the same chromatography resin using the same linear fluid velocity.

Maximum operating pressure

3 bar [0.3 MPa] (44 psi)

Ligand Coupling Method

Epoxy activation

Matrix

Rigid, highly cross-linked agarose

Average particle size

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~ 85 µm
Ligand
Recombinant protein A (E. coli)
Dynamic binding capacity
~ 30 mg human IgG/mL medium
Recommended flow rate
< 500 cm/h
Recommended column height
100 mm
Chemical stability
No significant change in chromatographic performance after 1 week storage using 8 M urea, 6 M guanidine hydrochloride, or 20% ethanol.
pH working range
3 to 10
CIP stability
2 to 12
Temperature stability
2°C to 40°C
Cleaning-in-place
Precipitated or denatured substances: 1. Wash with 2 column volumes (CV) of 6 M guanidine hydrochloride, contact time at least 10 min. 2. Wash immediately with at least 5 CV filtered start buffer. or 1. Wash with 2 CV 50 mM NaOH of 1.0 M NaCl or 50 mM NaOH in 0.5 M Na2SO4 , contact time ~ 10 min. 2. Wash immediately with at least 5 CV filtered start buffer. Hydrophobically bound substances: 1. Wash with 2 CV 50 mM NaOH 1.0 M NaCl or 50 mM NaOH in 0.5 M Na2SO4 , contact time ~ 10 min. Wash with 2 CV nonionic detergent (e.g., conc. 0.1%), contact time ~ 10

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min. 2. Wash immediately with at least 5 CV start buffer. or 1. Wash with 3 to 4 CV 70% ethanol or 30% isopropanol, contact time ~ 10 min. Increasing gradients may be applied to avoid air bubble formation when using high concentrations of organic solvents. 2. Wash immediately with at least 5 CV start buffer.

Sanitization

1. Wash the column with 0.1 M acetic acid in 20% ethanol. 2. Leave the column in contact with the solution for 1 hour. 3. Wash with at least 5 CV sterile start buffer at pH 7 to 8. or 1. Wash the column with 70% ethanol. 2. Leave the column in contact with the solution for 12 hours. 3. Wash with at least 5 CV sterile start buffer at pH 7 to 8.

Scaling up

After optimizing the method at laboratory-scale, the process is ready for scaling up. Scale-up to a larger column is typically performed by keeping the bed height and flow velocity (cm/h) constant while increasing the bed diameter and the flow rate (mL/min or L/h). For quick small scale-up of purification, two HiScreen columns can be connected in series with a union to give a 20 cm bed height.

Pack size

1 × 4.7 mL

Maximum flow velocity

500 cm/h

Dimensions

7.7 × 100 mm

Column volume

4.7 ml

Column i.d.

7.7 mm

Column hardware pressure limit

0.8 MPa (8 bar)

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