HiTrap Fibro and HiScreen Fibro PrismA protein A chromatography

Product Information

Cat#No#	Hi-034A

Product Overview

HiTrap Fibro and HiScreen Fibro PrismA are protein A fiber chromatography units for rapid cycling chromatography purification of mAbs for research and process development applications. Ultrafast purification enables cycle times under 5 minutes compared to hours for resins. HiTrap Fibro PrismA is primarily intended for reserach use and HiScreen Fibro PrismA is primarily intended for early process development:

Purify mAbs and Fc-containing fragments using rapid cycling chromatogrpaphy. Cycle times are less than 5 minutes compared with hours for chromatography resins.

Increase throughput up to 20-fold over that for resin-based chromatography and perform a full life time study in one day. This cuts weeks from lead times in process development.

Achieve high-throughput purification of up to 500 mAbs per week for cell line or candidate screening.

Run Fibro PrismA units on an ÄKTA chromatography system for real-time UV, pH and conductivity detection.

Description

Protein A fiber chromatography unit for rapid cycling chromatography in research and process development applications.

Applications

The Fibro PrismA units have a binding capacity of approximately 30 mg/mL at residence times of 1.5 to 7.5 seconds.

Good capacity, low ligand leakage, plus the rigid matrix, make Fibro PrismA units ideal for the purification of monoclonal antibodies. The ready to use format is well suited for preparative purifications when short cycle times, high productivity and flexibility is important. Because of the high flow rates and the high throughput, the units are especially useful for cell cultures with low expression levels. The disposable/single batch format eliminates the need for sanitization.

Maximum operating pressure

1 Mpa (10 bar, 145 psi)

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Sample preparation
1.Adjust the sample to the composition of the start buffer with additional salt using one of these two methods: a. Dilute the sample with binding buffer with additional salt. b. Perform a buffer exchange using a prepacked column for desalting. 2.Filter the sample through a 0.22 or 0.45 µm filter or centrifuge immediately before loading it to the Fibro unit. This prevents clogging and increases the lifetime of the unit when loading large sample volumes.
Matrix
Derivatized electrospun cellulose fibers
Ligand
PrismA ligand (alkali-stabilized protein A derived from E. coli)
Coupling chemistry
Single point attachment
Dynamic binding capacity
~30 mg IgG/mL matrix
Recommended flow rate
HiTrap Fibro PrismA(16 mL/min (40 MV/min)); HiScreen Fibro PrismA(30 mL/min (8 MV/min))
Chemical stability
Compatible with aqueous buffers commonly used for protein A chromatography
Chemical compatibility
Compatible with chemical compounds specified in Chemical compatibility.
pH working range
3 to 12
pH CIP range
2 to 14
CIP stability

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The alkali-tolerant protein A-derived ligand allows the use of 0.5 to 1.0 M NaOH for Cleaning-In-Place (CIP) in each purification cycle. In case of challenging mAb harvest materials even 1.5 to 2.0 M NaOH can be used.

Temperature stability

4°C to 35°C

Storage

Store HiTrap and HiScreen Fibro PrismA in 20% ethanol at 2°C to 8°C.

Warning

Do not exceed the maximum operating pressure, 1.0 MPa.

Notes

1.Cell culture supernatant that has been stored either in liquid form or as frozen material must always be sterile filtered into a sterile container just before loading to the Fibro unit.
2.Decrease the flow rate at low temperatures or when viscous solutions are used.

Binding buffer

20 mM phosphate, 150 mM NaCl, pH 7.4

Elution buffer

50 mM sodium acetate, pH 3.5

Equilibration

Equilibrate the unit with binding buffer until the UV baseline, pH, and conductivity are stable, and then auto-zero the UV signal.

Elution

Stepwise elution allows the target antibody to be eluted in a more concentrated form, reducing buffer consumption, and shortening cycle times.

Cleaning-in-place

HiTrap Fibro PrismA:
1. CIP with 8 mL NaOH (0.5 to 1.0 M), flow rate 16 mL/min for a contact time of 0.5 min, or 8 mL/min for a

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contact time of 1 min.
2. Wash immediately with 6 mL binding buffer at the same flow rate as in step 1.
3. Re-equilibrate with binding buffer, 16 mL/min, for or until the effluent pH and conductivity reach the values for the binding buffer.
HiScreen Fibro PrismA:
1. CIP with 4 MV of NaOH (0.5 to 1.0 M), flow rate 30 mL/min (8 MV/min) or 15 mL/min (4 MV/min) for a contact time of 0.5 or 1 min. 2. Wash immediately with 2 MV binding buffer at the same flow rate as in step 1.
3. Re-equilibrate with binding buffer, 30 mL/min, for 10 MV, or until the effluent pH and conductivity reach the values for the binding buffer.

Purification procedures
A CHO (Chinese hamster ovary) cell culture supernatant sample containing mAb 1 was purified using a HiTrap Fibro PrismA unit (0.4 mL) and a HiTrap MabSelect PrismA column (1 mL) on an ÄKTA pure 25 system. Performance of the Fibro PrismA unit was comparable to that of the column, as shown by similar recovery, host cell protein (HCP) removal, aggregate concentration, and protein A leakage.
Pack size
HiTrap Fibro PrismA(1 × 0.4 mL); HiScreen Fibro PrismA(1 × 3.75 mL)
BioProcess resin
HiTrap Fibro PrismA(0.4 mL); HiScreen Fibro PrismA(3.75 mL)

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