

## VIIISelect

### Product Information

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**Cat#No#** VI-385C

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### Product Overview

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VIIISelect is an affinity chromatography resin designed for the purification of recombinant  $\beta$  domain depleted factor VIII:

Highly selective for recombinant  $\beta$ -domain-deleted Factor VIII.

Efficient purification of recombinant  $\beta$ -domain-deleted Factor VIII with high yields and retained activity.

Excellent scalability.

Non-animal derived.

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### Description

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VIIISelect is an affinity resin designed for the purification of recombinant  $\beta$ -domain-deleted factor VIII, a key recombinant blood factor used for treatment of Hemophilia A. Due to the sensitive nature of the factor VIII molecule it is important to limit the number of steps in the downstream process. The high selectivity and yields obtained using VIIISelect enable a robust and efficient purification process with excellent purity obtained in one step.

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### Characteristic

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Efficient industrial-scale purification of recombinant factor VIII, with high yields and retained specific activity. High selectivity and excellent scalability.

Reduced regulatory concerns (due to non-mammalian-derived product) in the production of FVIII for clinical applications.

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### Maximum operating pressure

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< 300 cm/h, < 200 kPa, BPG 300, bed height 20 cm

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### Ligand Coupling Method

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Amide linkage

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### Matrix

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Highly crosslinked agarose

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## VIIISelect

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**Average particle size**

~75 µm

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**Ligand**

Mr 13 000 recombinant protein produced in *S. cerevisiae*. Binds to β domain deleted factor VIII molecules.

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**Ligand density**

Approx. 0.7 mg/mL of resin

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**Coupling chemistry**

NHS

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**Dynamic binding capacity**

Approx. 20 000 IU FVIII/mL of resin.

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**Recommended flow rate**

Up to 300 cm/h at 30 cm bed height at 20°C using buffers with the same viscosity as water at < 0.3 MPa (3 bar).

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**Recommended column height**

20 cm

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**Chemical stability**

Stable to commonly used aqueous buffers.

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**pH working range**

3–10

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**CIP stability**

2–12

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**Temperature stability**

4°C to 30°C

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**Storage**

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## VIIISelect

4 to 8°C, 20% Ethanol

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### Elution buffer

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20 mM histidine, 20 mM calcium chloride, 1.5 M sodium chloride, and 0.02% Tween 80 dissolved in 50% ethylene glycol at pH 6.5.

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### Binding

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1. Pack the column with VIIISelect.
  2. Equilibrate with 10 CV (column volumes) of equilibration buffer.
  3. Load the sample in loading buffer. Recombinant factor VIII can be applied directly to the VIIISelect column from clarified cell lysates or supernatants.
  4. Wash with 5 CV of washing buffer 1.
  5. Wash with 5 CV of washing buffer 2.
  6. Elute with 5-10 CV of elution buffer.
  7. Regenerate the column with regeneration buffer.
  8. Perform CIP.
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### Equilibration

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10 mM histidine, 20 mM calcium chloride, 300 mM sodium chloride, and 0.02% Tween 80 at pH 7.0.

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### Elution

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1. Pack the column with VIIISelect.
  2. Equilibrate with 10 CV (column volumes) of equilibration buffer.
  3. Load the sample in loading buffer. Recombinant factor VIII can be applied directly to the VIIISelect column from clarified cell lysates or supernatants.
  4. Wash with 5 CV of washing buffer 1.
  5. Wash with 5 CV of washing buffer 2.
  6. Elute with 5-10 CV of elution buffer.
  7. Regenerate the column with regeneration buffer.
  8. Perform CIP.
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### Cleaning-in-place

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## VIIISelect

The recommended protocol comprises initial strip of the resin at low pH, and then subjecting the resin to NaOH of low concentration for cleaning.

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### Sanitization

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PAB (120 mM phosphoric acid, 167 mM acetic acid, 2.2 % v/v benzyl alcohol) is used for final sanitization of the resin. PAB solution is sensitive to light and should be freshly made not to damage the resin. PAB solution should be stored in a dark bottle and kept no longer than for a week. PAB solution has a pH of < 2, and resin stability can be limited in prolonged exposure at such a low pH.

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### Pack size

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25 mL

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### BioProcess resin

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Yes

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### Wash buffer

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Wash buffer 1: 20 mM histidine, 20 mM calcium chloride, 300 mM sodium chloride, and 0.02% Tween 80 at pH 6.5. Wash buffer 2: 20 mM histidine, 20 mM calcium chloride, 1.0 M sodium chloride, and 0.02% Tween 80 at pH 6.5..

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### Dimensions

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1 m

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