Sefinose™ Fast Flow

Product information for SF005-4F/SF006-6F:

Introductions:

Sefinose 4 Fast Flow and Sefinose 6 Fast Flow gel filtration media are based on highly cross-linked 4% and 6% agarose matrices, respectively, which give excellent physical stability and chromatographic qualities.The matrices were developed specifically to meet the high throughput demands of industrial process separations.Their rigidity permits high flow rates, which in turn give good resolution in a minimum of time. Sefinose Fast Flow matrices enable the rapid processing of large volumes and make these media ideal for use at process-scale. Sefinose Fast Flow gel filtration media are easy to work with, and tolerate working conditions of temperature, pH and chemical agents typically used in biopharmaceutical production processes. cleaned-in-place (CIP) to minimize production losses through column maintenance. The media can be autoclaved, if required,for complete sterilization.

Table 1

Resin	Sefinose™ 4 Fast Flow	Sefinose™ 6 Fast Flow
Cat#	SF005-4F	SF006-6F
Ingredient	4% Agarose	6% Agarose
Average size	45 – 165 µm	45 – 165 µm
Separation range	$6 \times 10^4 – 3 \times 10^7$	$1 \times 10^4 – 4 \times 10^6$
pH Stability (operation)	3 – 13	3 – 13
pH Stability (CIP)	2 – 14	2 – 14
Chemical Agents Stability	8 M Urea,6 M Gu-HCL, 70% Ethanol, 30% Isopropanol,30% Acetonitrile,1% SDS,2 M NaOH	
Pressure/Flow rate	(150 – 250 cm/h, High 10cm, diameter 5cm)	(200 – 400 cm/h, High 10cm, diameter 5cm)

Preparing Gel

Sefinose 4 Fast Flow and Sefinose 6 Fast Flow are supplied pre-swollen in 20% ethanol. Decant the excess ethanol and replace with working buffer before packing into columns.After packing in the column, the bed should be washed with at least 5 column volumes of starting buffer to remove the preservative.

Stability

Sefinose 4 Fast Flow and Sefinose 6 Fast Flow have high chemical and mechanical stability. Table 1 summarizes their characteristics.

Process-scale use

A list of columns recommended for Sefinose 4 Fast Flow and Sefinose 6 Fast Flow can be used ,such as BPG™ 200 column, XK 50/30 Column ,and so on, The operational flow rate should not exceed 80% of the packing flow rate. As for evaluation of packing and columns packed in other ways,such as Pressure packing (BPG Columns), Hydraulic pressure packing(INdEX columns), Suction packing(BPSS Columns), chromaflow packing(chromaflow columns),please read and follow the relevant column instruction manuals carefully.

Process hygiene

Good process hygiene ensures the safety and integrity of the final product by removing or controlling any unwanted substances which might be present or generated in the raw material, or derived from the purification system itself.Good process hygiene also has a positive effect on process economy by preventing successive build-up of contaminating material on the separation

media, thus increasing the life of the packed column.

Regeneration

Wash with 2 bed volumes of water, followed by 2–3 bed volumes of starting buffer. A complete cleaning-in-place (CIP) procedure is recommended after approximately 5 cycles, depending on the starting material.

Cleaning-in-place

Cleaning-in-place is the removal from the purification system of very tightly bound, precipitated or denatured substances generated in previous production cycles. In some applications, substances such as lipids or denatured proteins may remain in the column bed and not be eluted by the regeneration procedure. A specific CIP protocol has to be designed according to the type of contaminants known to be present in the feedstream. Recommended procedures for the removal of these contaminants without dismantling the column are described below. Column performance is not significantly changed by CIP procedures for at least 100 cycles.

1. Protocol to remove precipitated proteins:
   Wash the column with 4 bed volumes of 1.0–2.0 M NaOH solution at 40 cm/h, followed by 2–3 bed volumes of water.
2. Protocol to remove strongly bound hydrophobic proteins,lipoproteins and lipids:

- Wash the column with 4–10 bed volumes of up to 70% ethanol or 30% isopropanol. (Apply gradients to avoid air bubble formation when using high concentrations of organic solvents.)
- Alternatively, wash the column with detergent in a basic or acidic solution. For example, use 0.5% non-ionic detergent in 1.0 M acetic acid. Wash at a flow rate of 40 cm/h. Residual detergent can be removed by washing with 5 bed volumes of 70% ethanol.

Sanitization and sterilization

Sanitization using NaOH reduces microbial contamination ofthe media bed to a minimum without dismantling the column.The CIP procedures recommended above also sanitize Sefinose Fast Flow media effectively: A concentration of 1.0–2.0 M NaOH with a contact time of 30–60 minutes has proved effective for most microbial contamination.For sterilization of media, dismantle the column and autoclave at 121°C for 20 min..Remember to sterilize the column parts before reassembling and packing the column.

Storage

For longer periods of storage, e.g. weeks, we recommend that the media be stored at 3-8°C in 20% ethanol.