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Application Note

November 30, 2021

Keywords or phrases
Recombinat Protein, Proteins, Concentration, Diafiltration, Clarification, Hollow Fiber, Ultrafiltration, Single-use TFF

Recombinant Protein – Lab Scale Concentration – 2.27 mg/mL

Bengt Persson*
Sartorius Stedim North America Inc., 565 Johnson Avenue, Bohemia, NY 11716, United States

* Correspondence
Email: bengt.persson@sartorius.com

Abstract

This application note is focusing on the concentration and diafiltration of a 150 kD recombinant protein. With a target concentration of 2.27 mg/mL.

The goal was to determine the optimum operating conditions to maximize the retention of the protein at a favorable permeate flux rate.

The Reu-use line Explorer in 24-inch lengths and 30 kD MWCO with a 1.0 mm fiber ID was used for this trial. I was shown that no passage of the recombinant protein into the permeate happened, therefore nearly 100% of the product were retained. The average permeate flux rate was 60 LMH during the process. At the membrane loading of 75 Kg/m^2, the overall product recover was nearly 100%.

Introduction

In the following you will see a concentration of a 150 kD recombinant protein. The goal of this operation to determine optimum operating conditions to maximize the retention of the protein at a favorable permeate flux rate.

Materials

For this concentration and diafiltration of a 150 kD recombinant protein a Re-use line Explorer was used. The length of 24-inch and a MWCO of 30 kD and 1.0 mm fiber ID where chosen. Like all our Hollow Fiber modules the membrane consisted of modified Polyethersulfone (m-PES). The Explorer module has a diameter of 1.3 cm and a corresponding filter area of 0.0321 m^2 .

Details of used Hollow Fiber Module

Family	Re-use
Product Size	Investigator
MWCO | Pore Size	30 kD
Fiber ID	1.0 mm
Length	24 inch
Filter Area	0.0321 m^2
No. of Fibers	18
Recommended batch volume per module	250 – 1,500 mL
Diameter Module (cm)	1.3 cm
Feed | Retentate connectors	½-inch TC
Permeate connector	⅜-inch Hose Barb
Material	WA03010EXP24S0 (1-pack)

Methods

Feed:
- Recombinant Protein: 150 kD
- Concentration: 2.27 mg/mL

Details of Trial

Membrane & Module	Re-use line Explorer 24-inch 30 kD, m-PES, 321 cm^2, 1 mm fiber ID
Initial Feed Volume	2,400 g
Membrane Loading	2,400 g/321 cm^2 = ~75 kg/m^2
Process Objective	24 × concentration + 6 diavolumes (DV)
Process Flux	TMP control, 18 psig, 4000 sec^{-1}

Results

During optimization, the flux vs. TMP (Figure 1) is a smooth curve with no sudden increases or decreases in flux or TMP which shows the process conditions were optimum for this recombinant protein. Figure 2 for filtrate flux vs. concentration factor shows the filter could retain the recombinant protein at these process conditions.

Process Step:
Concentration

Element:
Explorer 16

HF Membrane:
30 kDa PES – 200 cm^2 – 1.0 mm ID

Initial Protein Concentration:
2.0 mg/ml

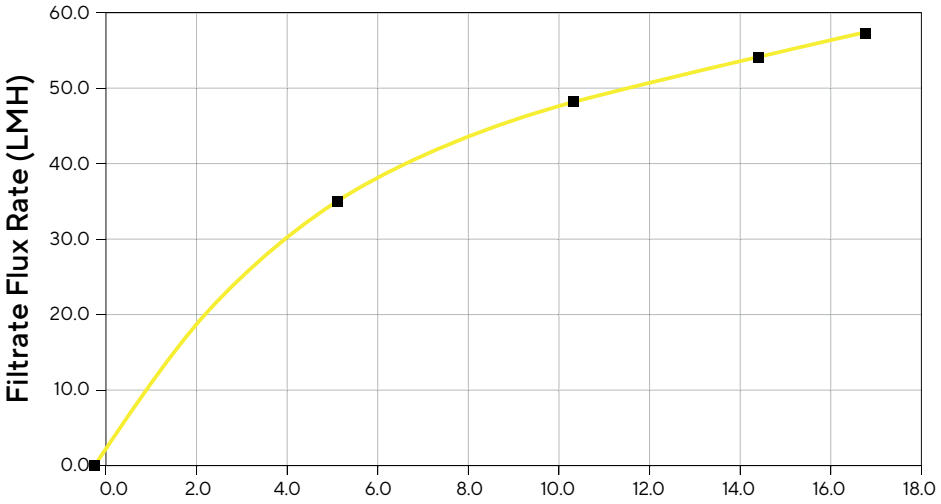

Figure 1: Filtrate Flux rate vs. TMP for fusion protein

Process Step:
Concentration

Element:
Explorer 16

HF Membrane:
30 kDa PES – 200 cm^2 – 1.0 mm ID

Initial Protein Concentration:
2.0 mg/ml

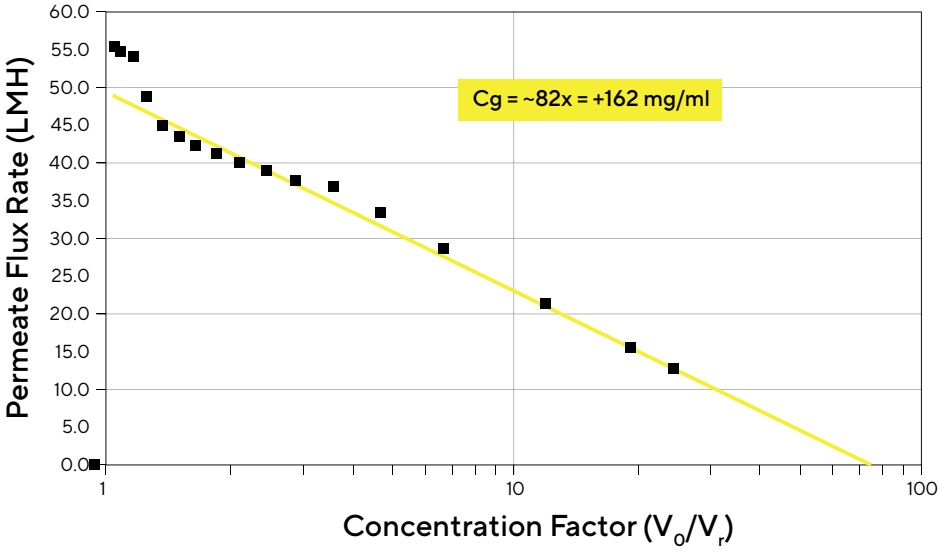

Figure 2: Filtrate flux profile for concentration of recombinant protein up to 162 mg/mL

Conclusion

The average permeate flux rate was 60 LMH during the process. At the membrane loading of 75 Kg/m², the overall product recover was nearly 100%.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
www.sartorius.com

Status 11 | 30 | 2021