# SEPRAFLO® ION-EXCHANGE RESINS

## Low-Cost Ion-Exchangers (Q & S) for Fast Protein Capture



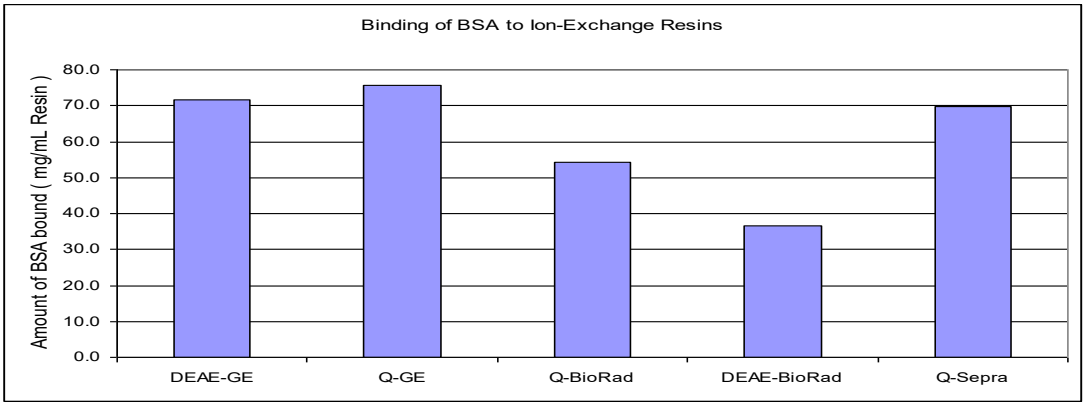
- ✓ *50% Higher Flow than "Fast Flow" media*
- ✓ *Costs 60% less*
- ✓ *Excellent Binding capacity*
- ✓ *Non-compressible*
- ✓ *Cleanable in 1M NaOH*
- ✓ *1000 cycles*

## Overview and Advantages

Sepragen's Sepraflo® Resins are designed for process scale separation of biological molecules. They can be run at very high flow rates, typically up to 50% higher than commonly used resins from other suppliers without causing compression like agarose or cellulosic beads or fracture or breakage like silica or macroporous PSDVB based beads. They have large nominal pore size, up to 700 A, that facilitates rapid mass transfer of large macromolecules and provides for high static and dynamic binding capacity. They are cleanable with 1N sodium hydroxide.

Sepraflo® resins consist of macroporous beads with nominal 50 micron size. They are rigid and can withstand pressures in excess of 500 psi. They can be supplied by Sepragen in batches of 100 liters on up. The resins are made of a hydrophilic copolymer of glycidyl methacrylate which is used predominantly in making contact lenses. The Sepraflo® resins are priced at a fraction of the price of competitive resins.

## Ion-Exchange Binding Capacity of Sepraflo®




The data above shows the binding capacity of Sepraflo® resins when compared with other commercially available resins. The resins show comparable binding with a model protein BSA. Binding capacities will vary for different proteins based on their charge, size and molecular weight, PI, tertiary structure, and the pH and ionic strength of the solution and the competitive binding effect of other counterions in solution.

# Application: Separation of Whey proteins using the Sepraflo® S Resin and Superflo® Column

## The Process

The process for producing WPI, alpha-enriched WPI, beta-enriched WPI, lactoferrin, lactoperoxidase and glycomicropeptides is shown in the figure below:

In order to capture the proteins on the resin, the pH of the whey is adjusted to a low pH. This will give all the proteins a positive charge, which will bind it to the negatively charged Sepraflo®-S resin.

The pretreated and pH-adjusted whey is loaded on the column after the column has been equilibrated. Then the column is washed with water and the proteins are eluted by means of patented 'Opposing Salt and pH' gradients.

The process fractions are processed in an ultra- and diafiltration plant, where the protein is concentrated to 25-27% total solids, while the permeate containing the buffer salt solution is processed in a reverse osmosis plant, concentrating it to 2-3% solids for re-use.

The protein concentrate is dried in a spray dyer, which can be of the tall-form type using an inlet air temperature of 180°C.

*The Sepraflo® resin combined with the Superflo® column process creates a cost effective next generation product opportunities, i.e. the isolation of Alpha Lactalbumin, Lactoferrin, Beta Lactoglobulin, GMP (GOS), IGs*

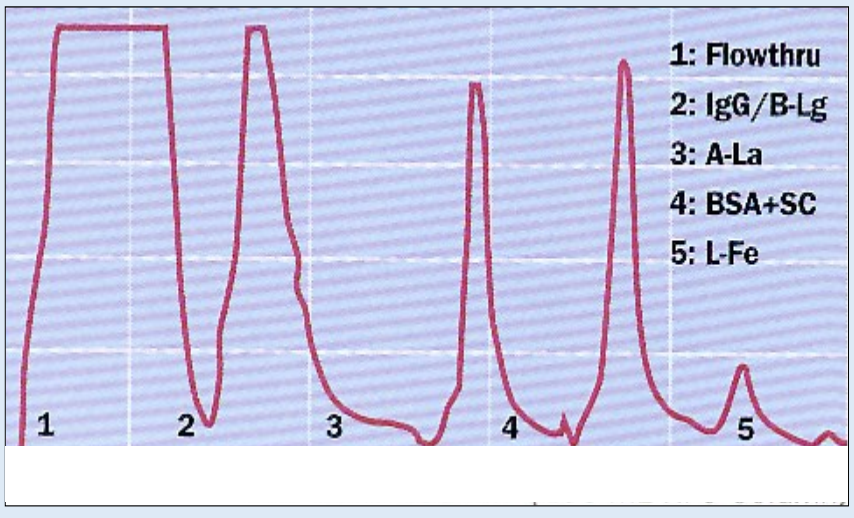
**Assumptions:**

***Volume:*** 250,000 liters of whey per day

***Whey type:*** Sweet cheese whey, pre-treated, past., normal comp.

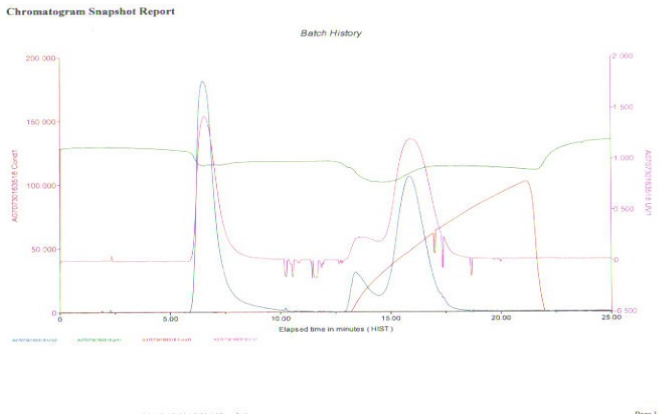
***Processing time:*** 24 hours per day, 300 days a year

| Ingredient/ Price | Traditional IEX | Sepraflo® Resins + Superflo® columns |
|---|---|---|
| Alpha lac<br>$20- 50/ Kg | Purity 20%- $80%<br>Cost $18/ Kg | Purity 70%<br>Cost $10-14/ Kg |
| Beta Lac<br>$ 5/ Kg | Purity 40%<br>Cost $3/ Kg | Purity 90%<br>Cost $4/ Kg |
| Lactoferrin<br>$ 1000+/ Kg | Purity 90%<br>Cost $50/Kg | Purity 90%+<br>Cost $30-$50/ Kg |



## Application: Antibody Separation on Sepraflo® S Resin

The graph below shows an antibody separation on a Sepraflo® cation exchange resin. Elution is done with a salt gradient.



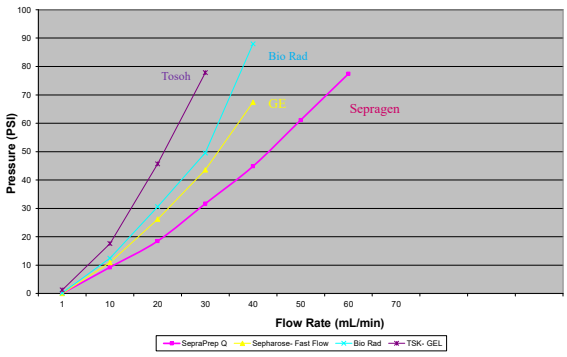

## Certificate of Analysis

| | |
|---|---|
| DATE | December 9, 2016 |
| PRODUCT | **SEPRAFLO® S RESIN** |
| LOT NUMBER | BGSS120901 |
| QUANTITY | 75 LITERS |

| *PARAMETERS* | *SPECIFICATIONS* | *RESULTS* | *REFERENCE* |
|---|---|---|---|
| Appearance | White Spherical Beads (Wet) | White Spherical Beads (Wet) | Visual Inspection |
| Total Exchange Capacity, Meq/ml (in $H^+$ form) | 220-300 Meq/ml | 282 | QA/FPR/09 |
| Moisture Content, % (in $H^+$ form) | 62 – 70% | 64.09 | QA/FPR/-05 |
| Static Protein Capacity, mg/ml | 65 – 85 mg/ml | 78.90 | QA/FPR-131 |
| Particle Size Distribution:<br>US Mesh<br>+ 140 MESH<br>+ 270 MESH<br>- 270 MESH | <br><br>5% Maximum<br>85% Minimum<br>10% Maximum | <br><br>4.70<br>93.10<br>2.20 | QA/FPR/-02 |
| Microscopic Analysis:<br>Whole Beads<br>Broken Beads | <br>95% Minimum<br>3% Maximum | <br>99.00%<br>1.00% | QA/FPR-06 |
| Organic Leachability Analysis:<br>DM Water Leachability, µg/ml<br>15% Ethanol Leachability, µg/ml<br>5% Acetic Acid Leachability, mg/ml | <br>1 Maximum<br>1 Maximum<br>1 Maximum | <br>Nil<br>0.40<br>0.82 | <br>FDA Publication 21 CFR 173.25 |

## Flow Rate vs. Pressure Performance

The data below shows a comparison of the flow rates that can be achieves with various resins at varying pressures. Sepraflo® resins consistently show higher flow rates than all other resins.




## Specifications:

Matrix: Glycidyl Methacrylate Copolymer

Functional Groups: Quaternery Amine and Sulphopropyl

Pore Size: ~700 angstrom

Particle Size: 20-100 microns (average 50 microns)

Binding Capacity BSA : 70 mgs/ml

## Sepragen Has What It Takes

Sepragen's pioneering spirit of innovation brings to you the Sepraflo® Resins. You can now use these high performance resins to enable rapid, cost –effective purifications of antibodies and other proteins. Call 510-475-0650 to discuss your needs today!

SEPRAGEN
*Innovators in Bioprocessing*

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