

## BioSeptra® DEAE, CM and SP Trisacryl® M/LS

### Ion Exchange Chromatography Sorbents

- Proven synthetic polymeric sorbents for process chromatography of proteins
- Highly hydrophilic and resistant to micro-organisms
- Adopted in several full-scale pharmaceutical manufacturing processes

#### The standard BioSeptra® synthetic ion exchange sorbent for protein separations

**Trisacryl** ion exchangers are spherical semi-rigid microbeads of acrylic copolymers designed for ion exchange chromatography of proteins. The strongly bound ion exchange groups which are an integral part of the polymer structure are found within its three dimensional structure. Each sub-unit of **Trisacryl** polymer possesses hydrophilic groups, which ensure biocompatibility and prevent non-specific adsorption.

#### A sorbent designed for optimal process economy in conventional chromatography

**Trisacryl** ion exchangers are macroporous, the ion exchange groups are easily accessible, and the sorbents provide high capacity for proteins. Industrial applications currently at production scale include the purification of recombinant polypeptides and proteins, plasma-derived fractions or sweet-whey derivatives.

The beads are semi-rigid and generate low back-pressure at typical low pressure liquid chromatography process flow rates. In contrast with a number of conventional ion exchange sorbents, **Trisacryl** ion exchangers require limited column volumes (1.5 to 1.8) for reequilibration, contributing to buffer savings and decreasing process time and cost.

#### Chemical Stability

**Trisacryl** sorbents are insoluble in all commonly used solvents. In addition, the matrix is resistant to denaturing agents (8 M urea, 6 M guanidine hydrochloride, and other chaotropic agents) and to non ionic detergents such as Triton® X-100, octylglucoside, and Tween® 80.

**Trisacryl** ion exchangers are acid resistant and can be used with both inorganic acids (i.e., 1 M HCl), as well as with organic acids, e.g., for the separation of peptides. Caustic solutions (NaOH) must be avoided.

#### Microbial Stability

**Trisacryl** is a totally synthetic matrix, therefore it is completely resistant to enzymatic and microbial degradation.

### Properties

	DEAE Trisacryl	CM Trisacryl	SP Trisacryl
Particle size (µm)	40 – 80 (M grade) ; 80 – 160 (LS grade)		
Exclusion limit (dt) <sup>(1)</sup>	> 10 <sup>7</sup>		
Nature of ionizable groups	diethylaminoethyl	carboxymethyl	sulfopropyl
Amount of ionic groups (µEq/mL)	320 – 370	190 – 230	190 – 250
pK of ionic groups	6.2 ; 10.7	4.7	1
Binding capacity (mg/mL)	> 75 (BSA) <sup>(2)</sup>	> 135 (lysozyme) <sup>(3)</sup>	> 80 (lysozyme) <sup>(3)</sup>
Working pH	1 – 11		
Microbial stability	Excellent		
Chemical stability	Stable to all solvents commonly used in liquid chromatography <sup>(4)</sup> and 6 M guanidine hydrochloride, 8 M urea		
Reequilibration volume (CV)	1.5 – 1.8		

<sup>(1)</sup> For globular proteins. <sup>(2)</sup> 10 mM Tris-HCl, pH 8.6, sample: 10 mg/mL BSA solution

<sup>(3)</sup> Sodium acetate, pH 5 containing 300 mM NaCl; Sample: 2.5 mg/mL lysozyme solution. <sup>(4)</sup> NaOH must be avoided

## Validation Support

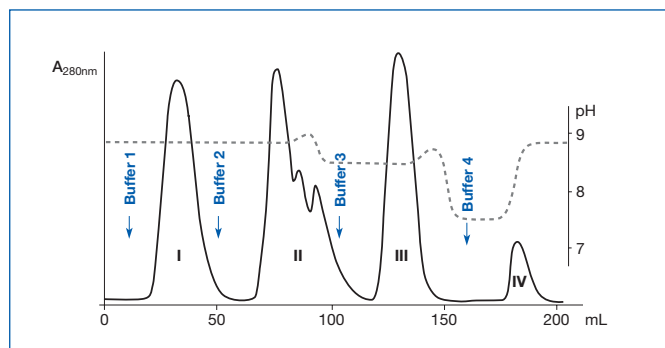
**Trisacryl** ion exchangers are commonly used for the production of approved injectable biomolecules from natural or recombinant sources, in columns up to several hundred liters.

Relevant FDA Drug Master Files:

- DMF No. 7830 for DEAE **Trisacryl**
- DMF No. 8039 for SP **Trisacryl**

## Application Example

### Purification of human IgG on DEAE Trisacryl M.



Column: 2.5 cm I.D. x 5 cm; Sample: 10 mL human plasma; Flow rate: 30 cm/h.

Buffer	Fraction	Composition	Purity
1 0.025 M Tris-HCl, 0.035 M NaCl, pH 8.8	I	IgG	99.5 %
2 0.025 M Tris-HCl, 0.075 M NaCl, pH 8.5	II	Transferrin Immunoglobulins $\beta$ -globulins Albumin	~ 70 % traces ~ 20 % traces
3 0.025 M Tris-HCl, 0.15 M NaCl, pH 7.5	III	Albumin $\alpha$ -globulins $\beta$ -globulins	~ 78 % ~ 15 % traces
4 <sup>(1)</sup> 0.1 M Tris-HCl, 1 M NaCl, pH 8.8	IV	Ceruloplasmin Factor VIII Factor IX Factor X	N.D.

(1) Regeneration buffer

Pure IgG are quickly obtained with an excellent yield. The results of this analytical experiment have been exploited for the set up of an industrial process for the production of IgG and albumin.

## Thermal Stability and Storage

Temperature of use	2 – 30 °C (36 – 86 °F)
Shipping temperature	Ambient
Storage temperature	2 – 30 °C (36 – 86 °F) (2 – 8 °C / 36 – 46 °F once opened)
Recommended storage solution (between runs)	Neutral buffer containing bacteriostatic agents such as 1 M NaCl and 20% (v/v) ethanol.

## References

1. Lebart, M.C., et al., J. of Biol. Chem. Vol. 268, No. 8 (1993) 5642.
2. Tusch, D., et al., Biochrom. 5 (1990) 30.
3. Séné, C., et al., ChimicaOggi (03/1990), 15.
4. Corthier, G., et al., J. Immunol. Meth. 66 (1984) 75.
5. Girot, P., Boschetti, E., J. Chrom. 213 (1981) 389.

## Ordering Information

	300 mL	1 L	10 L
DEAE Trisacryl M	25079-013	25079-054	25079-039
CM Trisacryl M	26708-016	26708-032	26708-024
SP Trisacryl M	25910-019	25910-027	25910-035
DEAE Trisacryl LS	-	26710-012	26710-020
CM Trisacryl LS	-	20030-011	20030-037
SP Trisacryl LS	-	26711-010	26711-028

Bulk quantities available on request



**New York - USA**  
+1 516.484.5400 phone  
+1 516.801.9548 fax  
pharmafilter@pall.com

**Portsmouth - Europe**  
+44 (0)23 9230 3303 phone  
+44 (0)23 9230 2506 fax  
BioPharmUK@europe.pall.com

**Cergy - France**  
+33 (0)1 34 20 78 00 phone  
+33 (0)1 34 20 78 78 fax  
bioseprainfo@pall.com

Visit us on the web at [www.pall.com](http://www.pall.com)

Pall, BioSeptra, Trisacryl, are trademarks of Pall Corporation.

**Filtration. Separation. Solution.** is a service mark of Pall Corporation.

\* Triton is a trademark of Dow Chemical Company.

\* Tween is a trademark of ICI Americas, Inc.

© indicates a trademark registered in the U.S.

© Pall Corporation 2004-2006