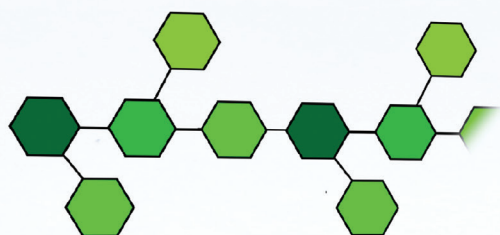
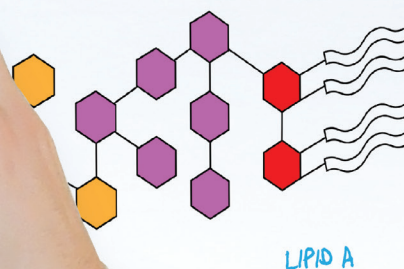


O-SPECIFIC POLYSACCHARIDE



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EtoxiClear™ - Endotoxin Removal Adsorbent

Cost effective and efficient endotoxin removal using a high performance synthetic ligand affinity chromatography adsorbent.

Supplied as an adsorbent slurry for column packing and an extensive range of disposable columns to suit your process, providing superior endotoxin removal from processing solutions and final products.



Search: EtoxiClear

Astrea
Bioseparations
Purity by Design

Our Technology

EtoxiClear™ comprises a novel synthetic ligand derived from Astrea Bioseparation Ltd Mimetic Ligand™ technology and is coupled to Astrea's proprietary PuraBead® 6XL base matrix. This proven technology provides a highly stable, robust and non-toxic chromatography adsorbent with high affinity for bacterial endotoxin and low protein binding. EtoxiClear™ is designed for use in endotoxin removal applications including process development, sample/buffer preparation and product polishing steps used during cGMP manufacture of biological molecules. EtoxiClear™ is exclusively manufactured by Astrea in our controlled environment manufacturing facility in accordance to an accredited ISO 9001 quality management system and is supported by a comprehensive regulatory support file.

Key Features

- Cost effective & scalable technology
- Endotoxin clearance to below 0.1 EU/mg protein
- Endotoxin clearance of ≤ 0.05 EU/mL from a range of buffers
- Compatible with a wide range of proteins
- Low protein binding (typically > 90% recovery)
- Available as an adsorbent slurry for column packing & an extensive range of disposable columns to suit your process requirements

Advantages

Performance Scalability

EtoxiClear™ has been demonstrated to effectively remove endotoxin from a purified immunoglobulin protein solution at both bench scale (5 mL column) and process scale (785 mL); utilising Astrea's 100 mm diameter Evolve™ Process Column.

Column volume	Initial endotoxin conc. (EU/mL)	Volume loaded (mL)	Total endotoxin loaded (EU)	Final endotoxin conc. (EU/mg) protein
5 mL	472	10	4,720	0.18
1600 mL	472	10	755,200	0.08

Load: IgG proteins solutions (~ 5 mg/mL) containing similar starting concentrations of endotoxin

Processing Capabilities

EtoxiClear™ is available either as an adsorbent slurry or in a range of disposable columns to suit your bioprocess needs. The table below can be used to estimate the column dimensions required to process your material.

EtoxiClear™ Columns			Processing rate (litres per hour)
Column volume	Diameter (cm)	Bed height (cm)	
785 mL	7	10	4.6
1.5 L	10	10	9.4
3.14 L	20	10	37.7

Specifications: EvolveD™ columns, 5 minute residence time.

Buffer Application

EtoxiClear™ can be used to remove endotoxin from a range of process buffers. The table below shows clearance from various buffers commonly used in cell culture applications, containing low starting concentrations of endotoxin (~ 20 EU/mL).

Buffer	Initial endotoxin conc. (EU/mL)	Volume loaded (mL)	Total endotoxin loaded (EU)	Endotoxin clearance (EU/mL)
PBS	23	300	6900	< 0.05*
Earles (EBSS)	16	400	6400	< 0.05*
Hanks (HBSS)	23	425	9775	$\leq 0.05^*$

*equal to or below limit of detection
BSS - balanced salt solution

High Endotoxin Clearance

EtoxiClear™ provides high endotoxin clearance with excellent protein recoveries from a wide range of proteins, as shown in the table below for HSA and IgG solutions (both at ~9 mg/mL).

Sample	Endotoxin concentration (EU/mg protein)	Protein recovery (%)
HSA load	23.6	-
HSA flow through	0.06	100

Endotoxin Clearance: 99.7%

Sample	Endotoxin concentration (EU/mg protein)	Protein recovery (%)
IgG load	8.3	-
IgG flow through	0.09	100

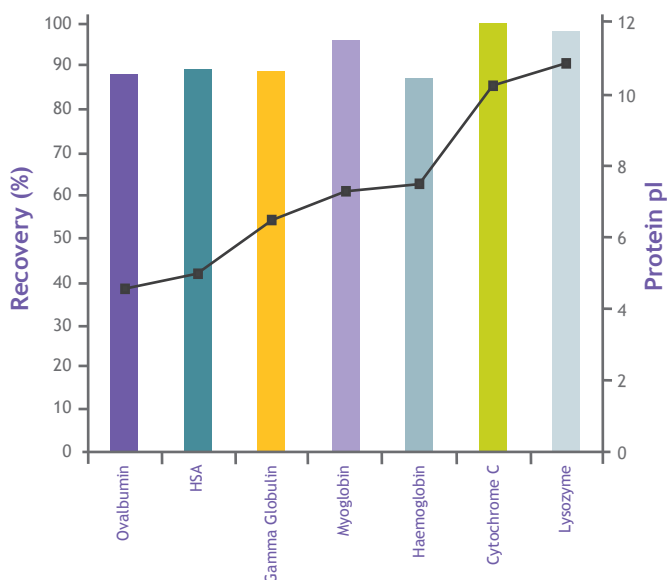
Endotoxin Clearance: 98.9%

Properties

Ligand:	Synthetic chemical ligand (proprietary)
Mean particle size:	100 ± 10 µm
Base matrix:	Cross-linked 6% near mono-disperse agarose (PuraBead® 6XL)
Dynamic endotoxin binding capacity:	> 1,000,000 EU/mL of adsorbent (120 cm/h, 5 minute residence time)
Maximum operational flow rate:	Up to 400 cm/h (EtoxiClear™ 5 mL EvolveR™ Column)
Recommended operational flow rate:	Up to 200 cm/h (dependent on column size)
Operational pH range:	pH 4.0 to pH 8.0
Chemical stability:	Stable in all commonly used buffers and solutions
Depyrogenation:	0.5 M to 1.0 M NaOH
Storage:	2 - 30 °C, 20% ethanol / 80% 0.1 M NaCl (v/v)

Low Protein Binding

Unlike ion exchange adsorbents, EtoxiClear™ exhibits very low protein binding and a wide range of proteins can be processed independently of their iso-electric point, with high protein recoveries (typically > 90% recovery), as shown below.



Ordering Information

For small orders up to 500 mL, please visit our webshop.

We also offer a range of larger pack sizes for supply of bulk resins into cGMP development and manufacturing scale processes.

Adsorbent Gel Slurry

Code	Description	Contents
3250-00010	EtoxiClear™	10 mL
3250-00025	EtoxiClear™	25 mL
3250-00100	EtoxiClear™	100 mL
3250-00500	EtoxiClear™	500 mL
3250-01000	EtoxiClear™	1000 mL

Pre-Packed Columns

Astrea offer a range of pre-packed columns from a 1 mL and 5 mL column kits and 5 mL and 50 mL EvolveR columns for research and development as well as a range of up to 6.28 L GMP ready columns for pilot to process scale manufacturing.

For more details please visit our website or for more information on this or any other supply related matters please do not hesitate to contact us.



Contact Us:

With sales and support offices in North America and Europe, R&D facilities in Cambridge, UK and manufacturing facilities located on the Isle of Man, British Isles and in Joliette, QC, Canada we are able to meet your needs and support your application wherever you are.

Sales and Technical Support

Please contact us for further sales or technical support information regarding any of our innovative biochromatography products and services.

Horizon Park, Barton Road,
Comberton, Cambridge,
CB23 7AJ, UK

Tel: +44 (0) 1223 433 800

Sales:	sales@astrea-bio.com
Technical support:	techsupport@astrea-bio.com
Quality support:	quality@astrea-bio.com
Website:	www.astreabioseparations.com

EtoxiClear® - Endotoxin Removal Adsorbent - V5

PuraBead® - this product or portions thereof is manufactured and sold under licence from GE Healthcare under US patents 6841097 and 7341202 and any corresponding patents for life sciences research and the purification/separation of naturally occurring or recombinant plasma derived proteins.

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The logo for Astrea Bioseparations features a stylized 'A' icon composed of two overlapping curved shapes. To the right of the icon, the word 'Astrea' is written in a large, bold, sans-serif font, and the word 'Bioseparations' is written below it in a smaller, regular, sans-serif font.