

EtoxiClear™ - Endotoxin Removal Adsorbent



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

.....supplied in an extensive range of disposable columns to suit your process and provide superior endotoxin removal from processing solutions and final products



ETOXICLEAR™ - Technology

EtoxiClear™ comprises a novel synthetic ligand derived from ProMetic BioSciences Ltd (PBL's) Mimetic Ligand™ technology and is coupled to PBL'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.

KEY BENEFITS:

- ✓ 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)
- ✓ Extensive pre-packed column range to suit your process requirements

ADVANTAGES

PERFORMANCE SCALABILITY -

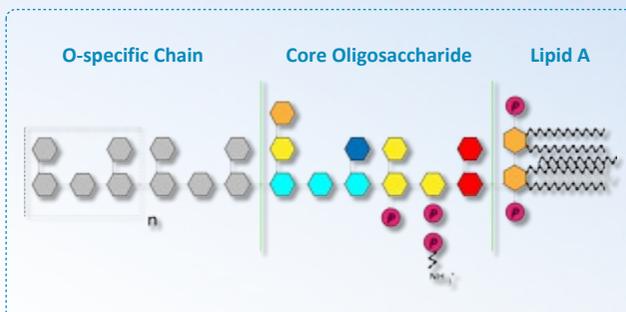
EtoxiClear™ provides comparable performance for endotoxin clearance (~0.1 EU/mg protein) across the column range, as shown in the table below, with excellent protein recoveries (up to 100%).

Column size	Initial endotoxin concentration (EU/mL)	Volume loaded (mL)	Total endotoxin loaded (EU)	Final endotoxin concentration (EU/mg protein)
5 mL	3322	5	16610	0.13
50 mL	1850	49	90650	0.03
500 mL	5089	520	2646280	0.08

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

BACKGROUND

Endotoxin or lipopolysaccharides (LPS) are highly toxic components of the cell wall of Gram-negative bacteria and are often present in significant amounts in bacterial cell expression systems such as *E. coli*.



A number of methods have been adopted for the removal of endotoxin based on adsorption, in particular ion exchange chromatography. Although downstream processing can significantly reduce endotoxin levels in the product, efficient and cost effective removal of residual endotoxin from biopharmaceutical preparations remains a challenge.

PROCESSING CAPABILITIES -

EtoxiClear™ is available in a range of pre-packed column sizes for bioprocess applications. The table below can be used to estimate the required column size to process your material.

EtoxiClear™ Columns			Processing Rate (litres per hour)
Volume	Diameter (cm)	Bed Height (cm)	
5 mL	0.8	10	0.06
50 mL	2.5	10	0.6
500 mL	8	10	6
1.5 L	14	10	19
3 L	20	10	38
7 L	30	10	85

Specifications: Axial columns, 5 minute residence time

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

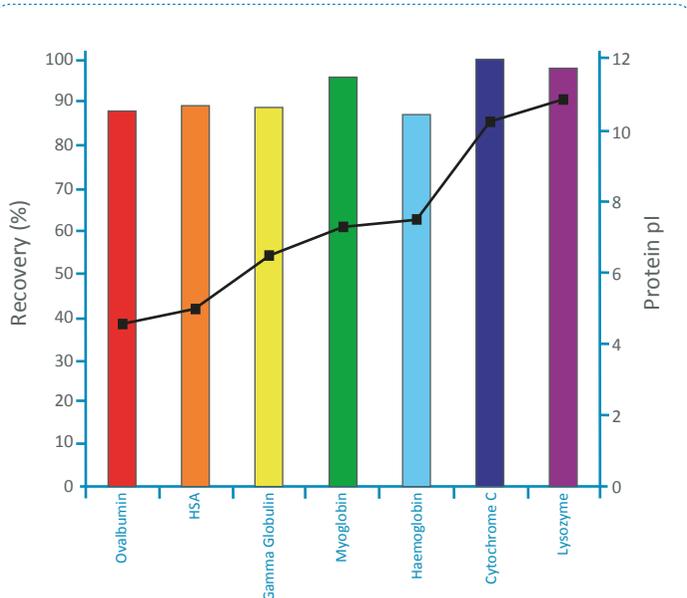
Endotoxin Clearance: **98.9%**

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/hr, 5 minute residence time)
Maximum operational flow rate:	Up to 400 cm/hr (EtoxiClear™ 5 mL Column)
Recommended operational flow rate:	Up to 200 cm/hr
Operational pH range:	pH 4.0 to pH 8.0
Chemical stability:	Stable in all commonly used buffers and solutions
Depyrogenation:	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, achieving high protein recoveries (typically >90% recovery), as shown below.



BUFFER APPLICATIONS -

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 concentration (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	≤0.05*

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

ORDERING

ETOXICLEAR™ PRODUCT RANGE -

EtoxiClear™ is available in a carefully selected range of disposable column sizes with bed volumes of 5 mL, 50 mL and 500 mL with a standard bed height of 10 cm, suitable for process development applications and polishing steps.

PBL also manufacture an extensive range of custom size columns designed specifically to suit your requirements (i.e. from 1 L to >10 L), allowing you to process larger volumes. Please contact us for more information via - sales@prometicbiosciences.com

ESTABLISHED MANUFACTURE -

EtoxiClear™ is exclusively manufactured by PBL 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.



CONTACT US

SALES & TECHNICAL SUPPORT

Please contact us for further sales or technical support information regarding EtoxiClear™ or any of our other innovative biochromatography products and services – let us show you how we can provide you with solutions to your biomolecular purification needs today:

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Endotoxin schematic source: <http://www.biozentrum.unibas.ch/~grzesiek/RESEARCH/home04.htm>

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