



EtoxiClear™



www.astreabioseparations.com

Astrea
Bioseparations

PURITY
by DESIGN



OUR TECHNOLOGY

Endotoxins are lipopolysaccharides (LPS) derived from the cell membrane of Gram-negative bacteria and are often found as impurities in final pharmaceutical products. Endotoxins elicit a variety of pathophysiological effects and according to the pharmacopoeia the maximum permitted level of endotoxin for intravenous products is 5 EU (endotoxin units) per kg adult per hour.

The removal of endotoxin is more challenging when associated with large protein molecules and while several methods adapted for specific products have been described for the removal of endotoxin from proteins, the methods based on selective adsorption are the most effective for the removal of LPS from a final product.

EtoxiClear™ is an affinity adsorbent designed for the removal of endotoxin and comprises a novel synthetic ligand derived from Astrea Bioseparations' Mimetic Ligand™ technology, coupled to 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 Bioseparations in our controlled environment manufacturing facility in accordance with 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
- Available as an adsorbent slurry for column packing & an extensive range of disposable columns to suit your process requirements

Advantages

- Stable chemical ligand
- Cross linked near monodisperse agarose beads (PuraBead® 6XL)
- Beads manufactured in-house giving security of supply and minimal lead times
- Dynamic binding capacity of $>1,000,000$ EU/mL (120 cm/hr, 5 min residence time)
- Stable in all commonly used buffer solutions
- Can be cleaned/ depyrogenated in 0.5 M to 1.0 M NaOH

Operational Range and Protein Recovery

EtoxiClear™ can be used to bind endotoxin across a wide pH range (4.0 - 8.0). Unlike ion exchange adsorbents, often used for endotoxin removal, 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).

PRODUCT FORMATS

Bulk Manufacture & Supply

Astrea Bioseparations supplies bulk adsorbents for developmental and regulated cGMP manufacturing applications in volumes sufficient to meet the requirements of the largest biomanufacturing processes.

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Adsorbent Gel Slurry

Pack Size	Product Code
25 mL	3250-00025
50 mL	3250-00050
100 mL	3250-00100
500 mL	3250-00500
1000 mL	3250-01000

Astrea Bioseparations also offer a range of pre-packed columns including 1 mL and 5 mL column kits and 5 mL and 50 mL Evolve®R columns, plus a range of larger pre-packed Evolve®D columns.

Code	Description
6646	EtoxiClear™ 1 mL Column Kit (4 x 1 mL)
6647	EtoxiClear™ 5 mL Column Kit (4 x 5 mL)
4251-00005	EtoxiClear™ 5 mL Evolve®R Column
4251-00050	EtoxiClear™ 50 mL Evolve®R Column



Commitment to Quality

Astrea Bioseparations is honored to support the biopharmaceutical industry with products and services that help bring life-saving and improving medicines to market. Regardless of process scale, we are ready to build Purity by Design into each process to ensure quality and speed to market.

Technical Support

Astrea Bioseparations is a world leader in adsorbent manufacture and chromatography development and can provide full product support in the use of EtoxiClear™ for optimization of endotoxin removal and the implementation for biopharmaceutical manufacture