

AMBERCHROM™ HPS60

CHROMATOGRAPHY RESIN

AMBERCHROM™ HPS60 Chromatography Resin allows you to achieve greater flexibility by reducing bottlenecks and increasing throughput in your mAb and protein manufacturing processes.

AMBERCHROM™ HPS60 Chromatography Resin is a monodispersed polymethacrylate strong cation exchange resin that will provide you with greater flexibility and increased throughput in your mAb and protein manufacturing processes. With an optimized bead size and pore structure, AMBERCHROM™ HPS60 media offers superior resolution of closely related impurities such as fragments and aggregates. Due to the rigidity of the bead, AMBERCHROM™ HPS60 media can be packed to higher bed heights than traditional agarose beads, resulting in greater flowrates and capacity in a smaller footprint. What's more, you don't have to worry about purchasing larger columns, as you can easily utilize your current capital equipment to deal with increasing upstream titers.

Decrease production bottlenecks

Increased pH and conductivity range of this resin allows direct loading of your feedstream and eliminates the need for dilution holding tanks.

Pack your beds higher

The rigidity of the beads allows you to pack higher bed heights, resulting in greater throughput in a smaller production footprint.

Increase your purity

Delivers excellent resolution of closely related impurities and improved removal of aggregates.

AMBERCHROM™ HPS60 Portfolio

AMBERCHROM™ HPS60 100 mL Media

- 100 mL of AMBERCHROM™ HPS60 media packaged in a bottle
- Available to evaluate AMBERCHROM™ HPS60 media packing or for process optimization studies

AMBERCHROM™ HPS60 1000 mL Media

- 1000 mL of AMBERCHROM™ HPS60 resin packaged in a bottle
- Pilot and medium-volume processing
- Perfect for scaling studies

AMBERCHROM™ HPS60 5 L and 50 L Media

- Large-volume processing

Regulatory Compliance and Supporting Documentation Package

- Validation Guide
- Certificates of Quality
- User Guides

AMBERCHROM™ HPS60 Media Capacity over a Broad Range of pH and Conductivity

As can be seen in Figure 1, AMBERCHROM™ HPS60 media maintains excellent capacity over a broad range of pH and conductivity. Alternative resins struggle to maintain capacity with slight changes in pH or salt concentrations. AMBERCHROM™ HPS60 media does not limit you to operating within a narrow window of manufacturing conditions.

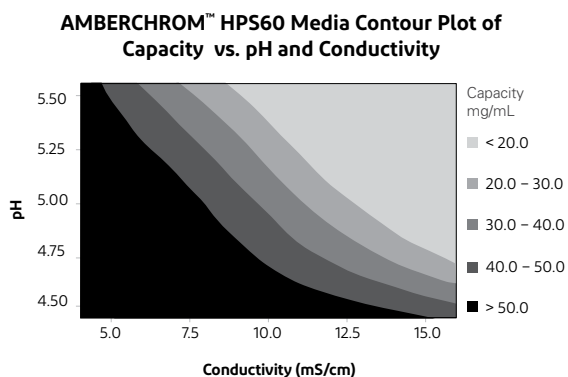


Figure 1. IgG at 3-minute Residence Time

Dynamic capacity was determined using a 0.66-cm x 7-cm omnit column packed with AMBERCHROM™ HPS60 media. Polyclonal human IgG was loaded onto the column at 3-minute residence time using a pH range from 3 – 5 and conductivities from 4 – 16 mS/cm (conductivities varied using addition of NaCl). The dynamic capacity was determined at a breakthrough of 5% of the starting IgG concentration.

Pressure Flow at 20-cm and 30-cm Bed Heights

AMBERCHROM™ HPS60 Chromatography Resin's semi-rigid construction and monodispersed beads allow bed heights of up to 30 cm. For comparison, traditional agarose beads typically have a maximum allowable bed height of 20 cm. This means that with AMBERCHROM™ HPS60 media, you can reliably achieve flowrates of 400 cm/h at 30-cm bed heights with reasonable operating pressures of 30 psi.

Unparalleled Application Support and Services

Our highly experienced applications support and purification experts not only can help you streamline your process development, scale-up, and validation work, but also assist you during production.

AMBERCHROM™ HPS60 Media Pressure Flow Characteristics

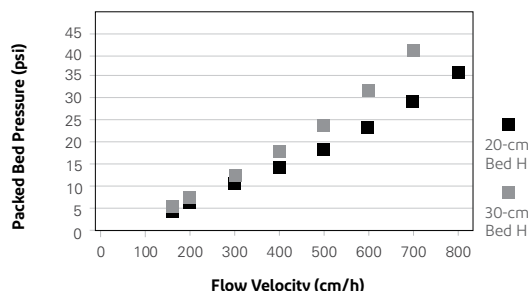


Figure 2. AMBERCHROM™ HPS60 Pressure Flow Properties

Pressure flow properties were tested using a 40-cm diameter QuikScale® column. AMBERCHROM™ HPS60 media was flow packed at 600 cm/h using RO water with 50-mM sodium chloride at room temperature. Salt pulse experiments demonstrated adequate HETP and asymmetry for both 20-cm and 30-cm bed height packing.

AMBERCHROM™ HPS60 Media Characteristics

Resin Bead	Crosslinked polymethacrylate (semi-rigid), monodispersed
Particle Size	58 µm
Ligand	Sulfonic acid functional group, an "S" type strong cation exchanger Ion exchange capacities of 210 – 300 µmol/mL

Properties

Operating Conditions	Typical flowrate at 30 psi in a 40-cm diameter column
AMBERCHROM™ HPS60 media 20-cm bed height	600 cm/h
AMBERCHROM™ HPS60 media 30-cm bed height	400 cm/h
Maximum Operating Temperature	4 – 30°C
Operating Buffers	Stable to all common buffers; including 1 M NaOH, 70% Ethanol
pH Stability Range	pH 1 – 13
Regeneration	1 – 2 M NaCl
Sanitization	0.1 – 0.5 M NaOH
Storage Conditions	AMBERCHROM™ HPS60 media is packaged in 20% ethanol as 50% slurry. Store between 4°C and 30°C. Please note: DO NOT FREEZE.
Good Manufacturing Practices	This product was manufactured in a facility that has been audited by and which adheres to Good Manufacturing Practices.
ISO® 9001 Quality Standard	This product was manufactured in a DuPont facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.
Animal Origin Statement	All Component materials used in the manufacture of this resin are either animal free or in compliance with EMEA/410/01.

Ordering Information

Description	Primary Use	Qty/Size	Catalog No.
100-mL Resin	Bench-top Packing and Process Development	1 x 100 mL	00011007652
1000-mL Resin	Packing and Scaling Trials	1 x 1000 mL	00011007787
5000-mL Resin	Small-scale Manufacturing	1 x 5000 mL	00011007789
50-L Resin Bulk Drum	Large-scale Manufacturing	1 x 50 L	00010366195



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