

DuPont Resins for Downstream Drug Purification

Collaborating with discovery labs, process research, scale-up, and manufacturing teams to enable complicated purifications and separations for therapeutics and diagnostics



About Us

DuPont is a global market leader in separation and purification solutions and offers a broad range of reverse phase, adsorbent, and ion exchange resins to help you reach your purity, yield, and throughput needs for traditional and emerging therapeutics. We envision a wellness-optimized world where our science-based approach to product design and manufacturing helps life science companies diagnose, manage, and cure diseases around the world, resulting in better outcomes for patients and life science companies alike.

Built upon our heritage in the resin powerhouses of Rohm and Haas and Dow, we have a long history in resin development and manufacturing that allows us to address complex separations and purifications across a wide range of application spaces, from fermentation downstream operations and synthetic and semi-synthetic manufacturing to PCR, gene-editing, and vaccines.

Our manufacturing expertise delivers products with consistent performance batch after batch, giving you the ability to scale up your purification processes through all stages of drug development from benchtop through to full commercial-scale production.

Our products can be used to:

- Purify and concentrate process streams
- Remove impurities from raw materials
- Adjust pH or ionic form (e.g., stabilizing peptides)
- Decolorize process streams

Table 1 shows a few examples of applications and processes that benefit from our products.

Together, we can
create a Wellness-
Optimized World



Table 1: DuPont Life Sciences Product Families for Biopharmaceutical and Pharmaceutical Manufacturing

	DuPont™ AmberChrom™ XT Chromatography Resins	DuPont™ AmberChrom™ CG Chromatography Resins	DuPont™ AmberChrom™ Fine Mesh Ion Exchange Resins	DuPont™ AmberChrom™ Profile Column	DuPont™ AmberLite™ XAD™ Polymeric Adsorbents	DuPont™ AmberLite™ Ion Exchange Resins
Market Applications						
Small molecule APIs	⊙	⊙	⊙		⊙	⊙
Oligonucleotides	⊙	⊙		⊙		
Peptides	⊙	⊙	⊙	⊙		
Vaccines			⊙		⊙	⊙
Vitamins					⊙	⊙
Plant Extracts		⊙	⊙		⊙	
Animal Extracts						⊙
Diagnostics	⊙		⊙	⊙	⊙	
Medical Devices		⊙				
Function						
Chromatographic separation	⊙	⊙	⊙	⊙		
Capture-Concentrate		⊙	⊙		⊙	⊙
Purification	⊙	⊙	⊙	⊙		⊙
Polishing	⊙			⊙		
pH Adjustment			⊙			⊙
Desalting			⊙		⊙	
Downstream Process Type						
Adsorption	⊙		⊙		⊙	⊙
Ion Exchange Chromatography			⊙			⊙
Reverse Phase Chromatography	⊙	⊙		⊙	⊙	

DuPont™ AmberChrom™ Chromatography Resins

DuPont™ AmberChrom™ chromatography resins are macroporous polymer resins designed for reverse phase chromatography of small molecules, peptides, and oligonucleotides. With a broad operating range and good chemical resistance to cleaning procedures, these polymeric reverse phase resins are excellent alternatives to reverse phase silica resins and give consistent performance cycle after cycle.

Resins are available in a range of options to fit diversified requirements for purity, resolution, and throughput in manufacturing processes, giving end-users flexibility to design purification processes suited to their individual needs. These resins were developed for use in chromatography columns and can be used as bulk resin in batch adsorption mode as well. AmberChrom™ chromatography resins are supported by an appropriate quality and regulatory program. Regulatory support packages are available upon request and under confidentiality.

Key Features & Benefits:

Stable in a wide variety of solvent and mobile phase conditions

- Wide range of mobile phase systems (pH range 1-14, gradient solutions, salt choices) to design adsorption and desorption profiles for optimized capacity and selectivity
- Clean in place with aggressive acids or bases to remove foulants and facilitate sanitization
- Consistent performance across many cleaning cycles
- Suitable for use in common organic solvents used in manufacturing processes

Mechanically stable

- Low swelling under a variety of elution and cleaning conditions to maintain robust column efficiency
- Rigid construction to facilitate high flow rates for high throughput
- XT grades are designed to achieve high resolution and high capacity and are resistant to backpressures up to 60 bar

Broad range of particle designs

- Multiple options to balance efficiency, resolution, and yield across a portfolio of drug chemistries and molecular weight ranges
- Styrenic and acrylic choices to match the hydrophobicity needs of the target molecule
- Thermally-stable polymeric design rated for use up to 60 °C

Applications:

Reverse phase chromatography relies on selective adsorption/desorption of molecules to the resin. Selectivity can be tuned based on resin composition and the polarity of the mobile solvent phase. AmberChrom™ chromatography resins find extensive use in purification of oligonucleotides, peptides, and active pharmaceutical ingredients. Example applications include the following:

- Capture and purification of peptides (e.g., removal of desamido insulin from insulin)
- Purification of oligonucleotides from impurities (failure sequences, DMT-off, oxidation products, etc.)
- Final polishing to remove trace impurities in flow-through chromatography
- Detergent removal after viral inactivation
- Purification of terpenes and taxanes
- Cytokine removal from blood plasma
- Purification of Vitamin E (tocopherol acetate)
- Isolation and fractionation of drug targets from complex fermentation and natural product extracts

Because of the wide utility of these resins, they can be used to manufacture a variety of end-products, such as:

- Antibiotics
- Hormones
- Vaccines
- Nucleic acids and peptides (e.g., insulin)
- Oncology drugs
- mRNA
- Oligonucleotide therapeutics
- PCR-based diagnostic kits
- CRISPR kits
- Custom and stock oligonucleotide sequences
- Gene therapies
- Small-molecule therapeutics
- Vitamins

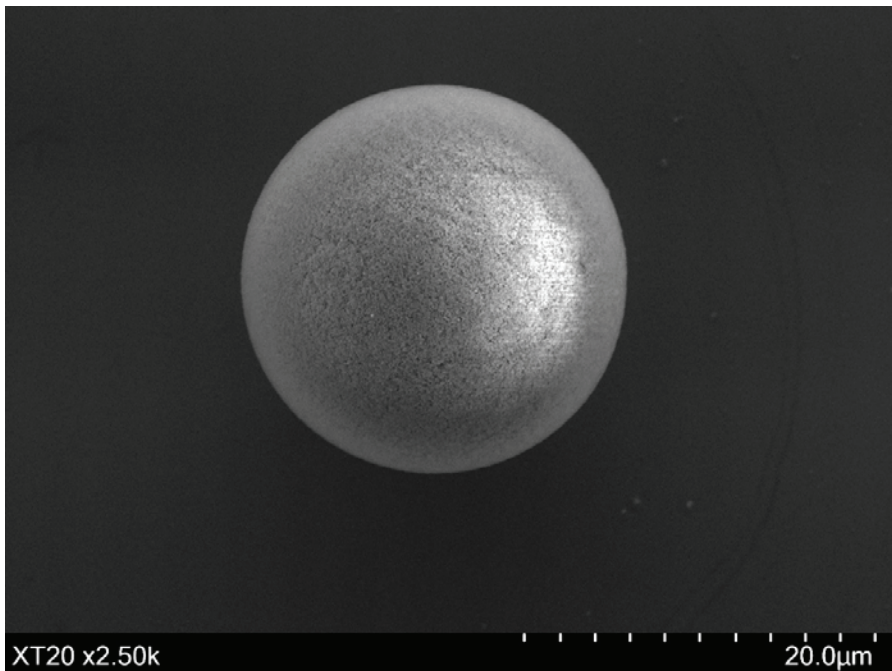
The typical properties of DuPont's AmberChrom™ chromatography resins are shown in Table 2 below. The XT grades offer the smallest particle sizes and are designed for downstream purification and polishing, where high resolution is required. The CG grades of resins are offered in small (S), medium (M), and coarse (C) size ranges to allow end-users flexibility to balance resolution and backpressure in their equipment. Sales specifications are available upon request.


Table 2. Product Characteristics of DuPont™ AmberChrom™ Chromatography Resins

Grade	Availability as Wet or Dry grade*	Chemistry	Average Particle size (µm)	Average Surface Area (m ² /g)	Mean pore size (Angstroms)	Size Exclusion Limit (kDaltons)	Max P (bar)
XT20	Dry	Crosslinked DVB	20	600	300	800	60
XT30	Dry	Crosslinked DVB	30	600	300	800	60
CG71S	Dry, Wet	Aliphatic Acrylic Ester	35	500	250	188	5
CG71M	Dry, Wet	Aliphatic Acrylic Ester	75	500	250	188	5
CG71C	Dry, Wet	Aliphatic Acrylic Ester	120	500	250	188	5
CG161S	Wet	Crosslinked DVB	35	900	150	70	5
CG161M	Dry, Wet	Crosslinked DVB	75	900	150	70	5
CG161C	Dry, Wet	Crosslinked DVB	120	900	150	70	5
CG300M	Dry, Wet	Crosslinked DVB	75	700	400	300	5
CG300C	Dry, Wet	Crosslinked DVB	120	700	400	300	5

* Bulk resins are sold in mass (g, kg) for dry grades and volume (mL, L) for wet grades. Dry resin is a minimum of 98% solids. Wet grades are sold as a 50% slurry by volume in an ethanol/water mixture (20/80 by volume).

DuPont™ AmberChrom™ Chromatography Resins



Many aspects of chromatography resin design, such as pore size, total surface area, chemical composition, and particle size, control the performance of reverse phase resins, and DuPont offers an assortment of product choices. Recommended starting grades for common applications are suggested below, but many factors play into system performance. We have a global team of highly skilled Technical Service & Development experts who can recommend grades for your applications and help you design mobile phase systems for your purification challenges.

Table 3. Recommended Starting Grades for AmberChrom™ Chromatography Resin for Select Applications

Grade	Small-molecules		Oligonucleotides		Peptides			Large Molecule APIs (vaccines, mAbs)	Medical Devices	Plant Extracts		
	>500 Dalton	<500 Dalton	<50 mer	50-mer or larger	Intermediate purification		Polishing	Detergent Removal	Blood plasma, cytokine removal	Polyphenolics	Flavonoids	Anthocyanins
					Large peptides	Small peptides						
XT20	⊙		●	⊙	⊙	⊙	●					
XT30	⊙		⊙	●	⊙	⊙	⊙					
CG71S	⊙				⊙	⊙						
CG71M	●				⊙	●		⊙				
CG71C	⊙				⊙	⊙		⊙		⊙	⊙	⊙
CG161S		⊙	⊙			⊙						
CG161M		●	⊙			●		●	⊙	⊙		⊙
CG161C		⊙	⊙			⊙		⊙	⊙			
CG300S	⊙		⊙	⊙	⊙	⊙						
CG300M	⊙		⊙	●	●	●			●	⊙		⊙
CG300C	⊙		⊙	⊙	⊙	⊙			⊙			

● = recommended starting grades

Select DuPont™ AmberChrom™ chromatography resins are available in pre-packed HPLC columns for laboratory use and small-scale production. These columns are excellent choices for drug discovery research, analytical separations, and custom oligonucleotide synthesis and production. Based on the same resin products as our bulk resin offerings, AmberChrom™ Profile™ columns perform consistently across a wide range of pH and

cleaning conditions and offers easy screening and predictable scale-up to all manufacturing scales. Each column is tested for pack quality to ensure efficient packing and every column has lot tracking from resin to column to customer to support your process development, clinical trial production, or small-scale manufacturing traceability needs.

Table 4. Recommended AmberChrom™ Profile™ Column Grades by Application

Grade	Product Characteristics			Recommended Applications			
	Resin	Column Type	Column size	Drug discovery research	Process Development	Oligonucleotide Production	Analytical Testing
Profile™ XT20	AmberChrom™ XT20	stainless steel	4.6 mm x 250 mm	●		●	●
		stainless steel	10 mm x 250 mm	●	●	●	
Profile™ XT30	AmberChrom™ XT30	stainless steel	4.6 mm x 250 mm	●		●	●
		stainless steel	10 mm x 250 mm	●	●	●	
		Glass	50 mm x 150 mm		●	●	
Profile™ CG300S	AmberChrom™ CG300S	PEEK	7.5 mm x 150 mm	●	●	●	



DuPont™ AmberChrom™ Ion Exchange Resin

DuPont™ AmberChrom™ ion exchange resins line are fine-mesh products with small spherical particles designed for rapid separations in both stirred-tank configurations and chromatography columns. Unlike ground resins, which have irregularly shaped particles and fines that restrict flow, the AmberChrom™ ion exchange resin beads are manufactured to a small diameter to provide an excellent balance of flow rate, column packing efficiency, and ease of handling. Because we have long history in manufacturing fine mesh products for large-scale processes, performance is reliable and scalable.

Products are available in the size ranges that correspond to the mesh sizes of the screens used to filter the resins. Sales specifications are available upon request.

- 20-50 mesh (> 300 µm), anion exchange resin only
- 50-100 mesh (approximately 150-300 µm)
- 100-200 mesh (approximately 75-150 µm)
- 200-400 mesh (approximately 35-75 µm)

The fine-mesh AmberChrom™ ion exchange resins are microporous (gel) copolymers of styrene and divinylbenzene (DVB) that are resistant to oxidation and reduction during operation and are insoluble in common solvents, giving end-users flexibility in solvent and buffer choices. AmberChrom™ ion exchange resin can handle many swell/shrink cycles, which means end-users can design complex separation processes with many bind-elute cycles.

Applications:

AmberChrom™ ion exchange resins are used in the purification and isolation of ionic small-molecule drugs, drug intermediates, fermentation broths, oligonucleotide purification, and peptides. Example uses include the following:

- Purification of erythromycin
- Separation of nucleotide mono-, di-, and tri- phosphates
- Separation and isolation of amino acids
- Detergent removal e.g., after viral inactivation or from raw materials
- Solid phase acid or base catalysis
- Salt-free pH adjustment
- Desalting and concentrating after fermentation
- Fractionation of ionic plant extracts
- Bulk media for drug analytics
- Removal of metal impurities such as residual metal catalysts (e.g., Pd, Pt, Rh)

These anion and cation exchange resins can be used to manufacture a variety of end-products:

- Macrolide antibiotics
- Hormones
- Vaccines
- Oligonucleotides
- Drug conjugates
- Crude purification of cell cultures
- Plant & animal extracts
- Peptides and amino acids

Key Features & Benefits:

Improved elution kinetics compared to traditional ion exchange resins

- Reduced elution volume
- Higher product elution concentration
- More efficient use of chemicals

Stable in a wide variety of chemicals

- Broad range of pH and buffer choices to optimize the elution profile
- Consistent performance across many cleaning cycles

Mechanically stable

- High flow rates for high throughput (up to 20 bar)
- Repeated regeneration cycles for long resin life
- High osmotic strength for use with a wide range of salts, pH values, and solvents

Broad range of particle characteristics

- Multiple options to balance kinetics, selectivity, and permeability to accommodate a variety of drugs types and sizes
- Excellent choice for purification of molecules below ~3000 Daltons
- Options for purification or isolation of anionic or cationic species

Table 5 provides a basic description of our fine-mesh anion exchange resins and cation exchange resins. Products are available in three different crosslink ranges across three particle size ranges to offer customers the ability to choose resins that balance their performance requirements and backpressure

limitations. Additionally, we offer a coarse particle size in the 4% crosslink level for those applications that value low backpressure and high flow rates over kinetics. Sales specifications are available upon request.

Table 5. Product Characteristics of DuPont™ AmberChrom™ Ion Exchange Resins

Grade	Functionalization	Ion Form	Crosslink Level	Molecular Weight Cutoff (Daltons)
Anion Exchange				
1x2 100-200 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	2%	~2700
1x2 200-400 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	2%	~2700
1x2 50-100 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	2%	~2700
1X4 100-200 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	4%	~1400
1X4 200-400 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	4%	~1400
1X4 20-50 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	4%	~1400
1X4 50-100 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	4%	~1400
1x8 100-200 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	8%	~1000
1x8 200-400 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	8%	~1000
1x8 50-100 Cl	N(CH ₃) ₃ ⁺	Cl ⁻	8%	~1000
Cation Exchange				
50Wx2 100-200 H	-SO ₃ ⁻	H ⁺	2%	~2700
50Wx2 200-400 H	-SO ₃ ⁻	H ⁺	2%	~2700
50Wx2 50-100 H	-SO ₃ ⁻	H ⁺	2%	~2700
50Wx4 100-200 H	-SO ₃ ⁻	H ⁺	4%	~1400
50Wx4 200-400 H	-SO ₃ ⁻	H ⁺	2%	~2700
50Wx4 50-100 H	-SO ₃ ⁻	H ⁺	4%	~1400
50Wx8 100-200 H	-SO ₃ ⁻	H ⁺	8%	~1000
50Wx8 200-400 H	-SO ₃ ⁻	H ⁺	8%	~1000
50Wx8 50-100 H	-SO ₃ ⁻	H ⁺	8%	~1000

Ion exchange performance depends on counterion type, crosslink level, and particle size, which together impact purification kinetics, pressure drop, selectivity, and process stability in flow-through column configurations. Table 6 illustrates recommended resin grades for a few example applications. Generally, the mid-size particle range (100-200 mesh) offers a good starting point for most applications but system-specific requirements

around kinetics, yield, and equipment capability may favor other grades. Contact our TS&D team for help with your unique needs. For additional guidance on how to use these resins, see *AmberChrom™ Fine Mesh Ion Exchange Resins Technical Manual For Fine Chemical and Pharmaceutical Columns* for guidance about packing and preparing AmberChrom Fine Mesh Ion Exchange Resins for use.

Table 6. Recommended AmberChrom™ Ion Exchange Resins Grades for Select Applications

	Small-molecule Purification (APIs, plant extracts, animal extracts)						Large Molecule APIs (vaccines, mAbs)	
	Anionic species			Cationic species			Detergent Removal	
	<1000 Dalton	<1400 Dalton	<2700 Dalton	<1000 Dalton	<1400 Dalton	<2700 Dalton	Anionic surfactant	Cationic surfactant
Anion Exchange								
2% crosslink	⊙	⊙	●					
4% crosslink	⊙	●					●	
8% crosslink	●							
Cation Exchange								
2% crosslink				⊙	⊙	●		
4% crosslink				⊙	●			●
8% crosslink				●				

● = recommended starting grades



DuPont™ AmberLite™ XAD Polymeric Adsorbent

DuPont™ AmberLite™ XAD polymeric adsorbents are macroporous hydrophobic resins (crosslinked DVB) that sequester products or impurities from other components in streams. Like the other polymeric chromatography resins in the DuPont portfolio, these resins have high crosslinking levels that offer excellent mechanical and chemical resistance, leading to robust performance in customers' purification processes, whether column processes or stirred-tank adsorption systems. Resin and captured impurities may be discarded after use or the resin may be regenerated for multiple uses, depending on the application. Products are available in a range of particle sizes, pore sizes, and surface areas to provide a variety of adsorption capacity and selectivity.

Key Features & Benefits:

Range of pore sizes and porosity

- Selectivity via size exclusion
- Flexibility in balancing adsorption capacity and desorption kinetics

Hydrophobic styrenic resins

- Selective removal of organic molecules from aqueous solutions and hydrophilic organic solvents
- Strong affinity for aromatic molecules

High crosslink density

- Low swelling for column efficiency and process stability
- Mechanically robust for long lifetimes during filtration and cycling

Applications:

In adsorption purification processes, molecules are preferentially adsorbed onto the surface and into the interior of the macroporous resins. Hydrophobic interactions drive attractive forces between these unfunctionalized resins and target molecules. Because the binding capacity increases with accessible surface area, particle size and porosity can impact the degree of interaction and therefore selectivity. Molecules must be small enough to access the interior surface area of these macroporous resins, so the pore diameter and swelling behavior under application conditions play important roles in controlling molecule selectivity. Adsorption purification processes can be designed to capture either impurities or products from process streams.

Desorption solvent choice impacts the total amount of desorption (i.e., yield), kinetics of desorption, and elution volume and therefore impacts product concentration.

Because of the versatility of these resins, they can be used to manufacture a variety of end-products in either reusable or single-use purification strategies. Example uses for AmberLite™ XAD polymeric adsorbents are the following:

Product capture via adsorption/desorption

- Insulin
- Bacitracin
- Vitamin B12 (desalting and concentration)
- Extraction of mogroside from Monk Fruit (*Siraitia grosvenorii*) and many other plant extracts
- Selective capture of Cephalosporin C from desacetyl Cephalosporin C and desacetoxyl Cephalosporin C in fermentation broths

Impurity removal

- Decolorization of Cephalosporin C
- Detergent removal from adenoviral vaccine
- Antibiotic removal in blood diagnostics
- Contrast agents

Example products that can be manufactured with AmberLite™ polymeric adsorbents include the following:

- Antibiotics (e.g., beta-lactams)
- Vitamins
- Vaccines
- Fermentation broths (e.g., purification of crude broth)
- Adenovirus vaccines and adeno-associated viral vectors
- Contrast agents
- Cyclic peptides (e.g, Bacitracin)
- Plant extracts

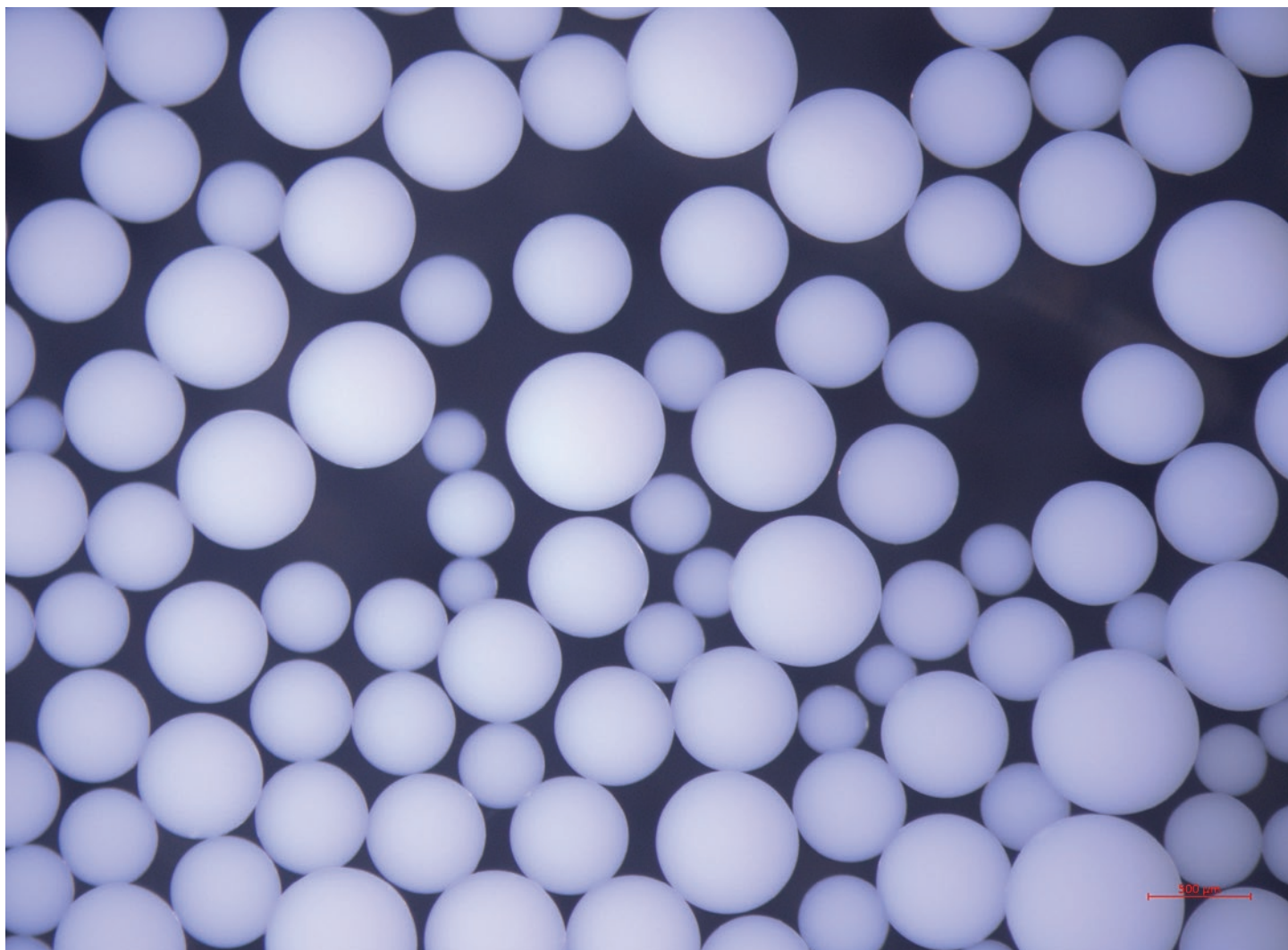
Typical characteristics of AmberLite™ Polymeric Adsorbent resins are given in Table 7, and example applications are shown in Table 8. Sales specifications available upon request.



Table 7. Product Characteristics of DuPont™ AmberLite™ Polymeric Adsorbents

Grade	Chemistry	Water Retention Capacity (%)	Average Particle size (µm)	Average Surface Area (m ² /g)	Average Porosity (mL/mL)	Mean pore size (Angstroms)	Swelling in acetone
AmberLite™ XAD4	Crosslinked DVB	54-60	490-690	750	0.5	100	20%
AmberLite™ XAD7HP	Crosslinked aliphatic acrylic	61-69	430-690	750	0.5	550	<5%
AmberLite™ XAD16N	Crosslinked DVB	60-68	560-710	800	0.6	150	20%
AmberLite™ XAD16HP N	Crosslinked DVB	62-70	600-750	800	0.6	150	20%
AmberLite™ XAD1180N	Crosslinked DVB	61-67	350-600	500	1.4	400	10%
AmberLite™ XAD1600N	Crosslinked DVB	66-73	350-450	800	1.4	150	20%

All resins are macroporous resins.



DuPont™ AmberLite™ XAD7HP

Table 8. Recommended AmberLite™ Polymeric Adsorbent Grades for Select Applications

	Small-molecule APIs			Diagnostics	Plant Extracts		Large Molecule APIs (vaccines, mAbs)	
	Antibiotics	Vitamins	Cyclic peptides	Blood purification	Tocopherols	Polyphenolics, Flavonoids, Anthocyanins	Terpenoids, terpene lactones, saponins	Detergent Removal
XAD4				⊙				⊙
XAD7HP						⊙	⊙	⊙
XAD16N	⊙		⊙	⊙	⊙	⊙		⊙
XAD1180N	⊙	⊙		⊙				
XAD1600N	⊙		⊙					⊙
XAD16HP N					⊙	⊙		

Ordering and Support Information

DuPont's purification resins for downstream drug purification are part of the Life Science and Specialties group within DuPont Water Solutions. We have a global team of sales, regulatory, quality, and technical experts who can help you with product inquiries for the Life Sciences industry. Regardless of whether your application is peptides, oligonucleotides, small molecule

APIs, or contrast agents, our scientists are ready to help you find solutions to your purification and separation challenges. Resins for Life Sciences are available in a range of packaging options, from small bottles and columns for benchtop research and analytical use to bulk resin drums for large-scale production. Please contact us at the website below for more information.

Have a question? Contact us at: dupont.com/water/contact-us



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