



AMBERCHROM® CG71

Chromatographic Grade Resin

For Chromatographic Purification

PRODUCT DATA SHEET

AMBERCHROM chromatographic media are macroporous, polymeric resins useful for adsorption and reversed phase liquid chromatography. They are designed for laboratory and process scale purifications of proteins, peptides, nucleic acids, antibiotics, and small molecular weight pharmaceuticals

AMBERCHROM CG71 chromatographic grade resin is an insoluble aliphatic (acrylic ester) polymer manufactured for high value chromatographic applications. Its high surface area, unique pore size and pore volume distribution make it ideally suited for separation of peptides. It is the most hydrophilic AMBERCHROM chromatographic resin.

AMBERCHROM CG71 has high capacity for many pharmaceutical compounds and has been commercially proven for many years. It is an excellent technical and economical alternative to RPC silica, and can be used in high resolution, low pressure chromatography.

AMBERCHROM CG71 is suitable for use in many pharmaceutical applications in the front end capture, purification, and desalting modes of operation depending on the particle size selected.

AMBERCHROM CG71 is available in three different particle size ranges (35, 75, and 120 microns), and is supplied as a slurry in 20 % ethanol.

AMBERCHROM CG71 is ideally suited for operation within the entire pH range, and can be easily cleaned in place (CIP) with most organic solvents and dilute acids and bases.

REGULATORY STATUS

A Material Regulatory Support (MRS) package is developed for AMBERCHROM CG71 resin users requiring assistance in supporting use of the resin in regulated applications. It is developed under CDA with users of this product and tailored to the customer's process parameters.

This material is manufactured under strict controls, and plant audits by potential customers are welcomed.

CLEAN IN PLACE

Unlike RPC silica, AMBERCHROM CG71, due to its polymeric nature and lack of bonded phase, can be cleaned in place (CIP) with most organic solvents and low concentrations of acids and bases. As the graph below demonstrates, there is no loss in capacity for insulin after prolonged exposure to 0.5 M NaOH. Tests spanned 180 days at ambient temperature and 100 days at 60°C.

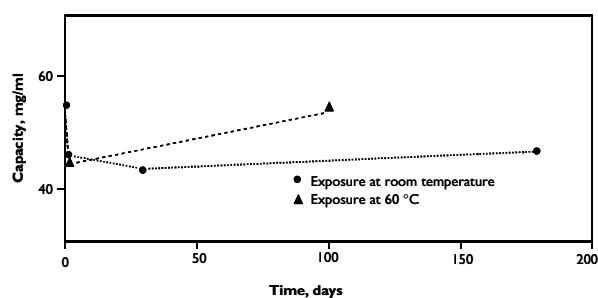


Figure 1: Insulin Adsorption

In addition to the excellent chemical resistance of AMBERCHROM CG71, it also exhibits low swelling in common solvents as shown below:

| Solvent | Swelling |
|--------------|----------|
| Water | 100 |
| Methanol | 102 |
| Ethanol | 105 |
| Isopropanol | 107 |
| Acetonitrile | 107 |
| Acetone | 106 |
| Toluene | 104 |
| Dry | 57 |

SEPARATION STRATEGIES FOR SMALL PEPTIDES

An application that demonstrates the advantages of the hydrophilic resin, AMBERCHROM CG71, is the purification of the small peptide, aspartame, from its precursors⁽⁸⁾, shown below.

The hydrophilic AMBERCHROM CG71 resin provides excellent results with high polarity aqueous alcoholic eluents. Although 50 percent methanol provided a quicker run time, 10 percent ethanol provided the highest solubility and loading of the mixture.

For comparison, the polystyrene based resins AMBERCHROM CG161 and AMBERCHROM CG1000 often work better with acetonitrile / water eluents.

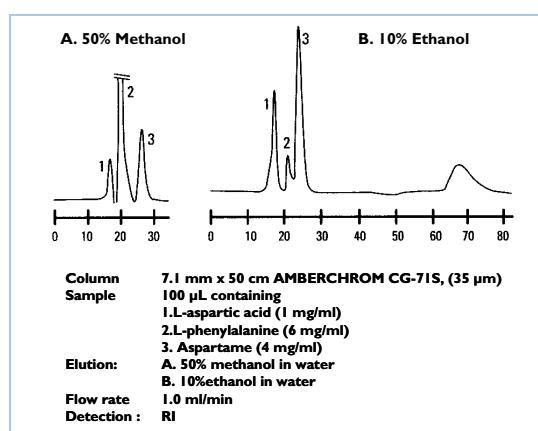


Figure 2: Purify Peptides with AMBERCHROM CG71

For small polar molecules such as amino acids, carboxylic acids, alcohols, ethers and dipeptides, the capacity factors, k' , with AMBERCHROM CG71 resin are listed in the table below. In general, non-aromatic amino acids are eluted quickly in water. When 10 percent ethanol is the eluent, instead of water, the retention times of weakly retained species increase and retention times of strongly held species decrease.

These data suggest that a shallow gradient from water to aqueous ethanol will effectively separate many non-aromatic species from aromatic species.

Capacity Factors For Selected Solutes: AMBERCHROM CG71

| Compound | In Water | In 10 % Ethanol |
|--------------------|----------------|-----------------|
| NaCl | 0 | 0 |
| Fumarate, disodium | 0 | – |
| L-Aspartic acid | 0 | 0.13 |
| Glutathione | 0 | 0.108 |
| L-Lysine | 0.018 | – |
| L-Glutamic acid | 0.021 | 0.1 |
| L-Cystine | 0.023 | – |
| Diglycine HCl | 0.026 | – |
| L-Arginine | 0.0928 | – |
| L-Alanine | 0.031 | – |
| Glycine | 0.038 | 0.037 |
| Cellobiose | 0.041 | 0.066 |
| L-Asparaginine | 0.041 | 0.161 |
| L-Serine | 0.044 | 0.056 |
| L-Hydroxyproline | 0.046 | 0.111 |
| L-Proline | 0.048 | 0.000 |
| Glucose | 0.051 | 0.069 |
| Fructose | 0.067 | 0.140 |
| Citric acid | 0.100 | 0.244 |
| L-Valine | 0.107 | – |
| L-Isoleucine | 0.197 | – |
| L-Methionine | 0.225 | 0.323 |
| L-Leucine | 0.230 | 0.220 |
| Methanol | 0.238 | 0.196 |
| Glycine anhydride | 0.263 | 0.257 |
| Ethanol | 0.494 | 0.302 |
| L-Tyrosine | 0.618 | – |
| L-Phenylalanine | 0.829 | 0.614 |
| Succinic acid | 1.40 | 0.896 |
| t-Butanol | 1.89 | 0.331 |
| L-Tryptophan | 4.40 | 1.770 |
| Aspartame | Did not elute* | 3.600 |
| Benzoic Acid | Did not elute* | 6.930 |

IR SPECTRUM OF AMBERCHROM CG71

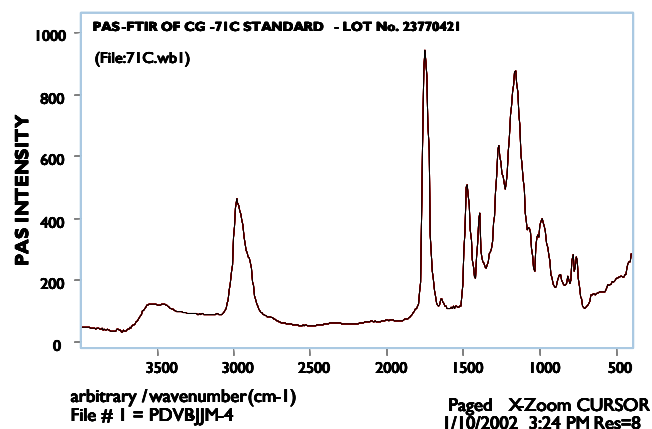


Figure 3: AMBERCHROM CG71 IR Spectrum

TYPICAL PHYSICAL PROPERTIES

| | |
|--------------------------------|---|
| Matrix _____ | Acrylic ester macroreticular adsorbent |
| Functional groups _____ | None |
| Physical form _____ | Opaque white beads |
| Shipping solvent _____ | 20% ethanol |
| Surface area _____ | 500 m ² /g |
| Pore size ^[1] _____ | 250 Å |
| Mean diameter _____ | S grade : 35 microns |
| | M grade : 75 microns |
| | C grade : 120 microns |
| | 1.7 |
| Uniformity coefficient _____ | Insoluble in dilute solutions of acids or bases |
| Chemical resistance _____ | and common solvents : IPA, ACN, MeOH. |
| _____ | |

^[1] Test methods are available on request.

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ORDERING INFORMATION

| Part Number | Description | Particle Size | Packaging |
|-------------|------------------|---------------|-----------|
| I0235573 | AMBERCHROM CG7IS | 35 µm | 25 mL |
| I0235574 | AMBERCHROM CG7IS | 35 µm | 100 mL |
| I0235575 | AMBERCHROM CG7IS | 35 µm | 1000 mL |
| I0097851 | AMBERCHROM CG7IS | 35 µm | 5 L |
| I0097850 | AMBERCHROM CG7IS | 35 µm | 50 L |
| I0235576 | AMBERCHROM CG7IM | 75 µm | 25 mL |
| I0235577 | AMBERCHROM CG7IM | 75 µm | 100 mL |
| I0235578 | AMBERCHROM CG7IM | 75 µm | 1000 mL |
| I0097855 | AMBERCHROM CG7IM | 75 µm | 5 L |
| I0097854 | AMBERCHROM CG7IM | 75 µm | 50 L |
| I0235579 | AMBERCHROM CG7IC | 120 µm | 25 mL |
| I0235580 | AMBERCHROM CG7IC | 120 µm | 100 mL |
| I0235581 | AMBERCHROM CG7IC | 120 µm | 1000 mL |
| I0097859 | AMBERCHROM CG7IC | 120 µm | 5 L |
| I0097858 | AMBERCHROM CG7IC | 120 µm | 50 L |

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WEB SITE: <http://www.amberchrom.com>



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