Product Data Sheet

# DUOLITE™ AP143/1073 Resin

Pharmaceutical Grade Anion Exchange Resin Powder
(Cholestyramine Resin USP)

## Description

DUOLITE™ AP143/1073[1] resin is an insoluble, strongly basic, anion exchange resin in the chloride form supplied as a dry, fine powder. DUOLITE™ AP143/1073 Resin is suitable for pharmaceutical applications either as an active ingredient or as a carrier for acidic (anionic) drug substances. A monograph for Cholestyramine Resin USP appears in the United States Pharmacopoeia/National Formulary.

DUOLITE™ AP143/1073 resin conforms to the compendial specifications.

A Drug Master file for this product is maintained with the United States Food and Drug Administration.

DUOLITE™ AP143/1073 Resin can be identified by infrared spectroscopy, as shown in the example Figure 1. Letters of authorization granting access to the file by FDA in support of NDA and ANDA submittals will be provided upon request.

DUOLITE™ AP143/1073 Resin is manufactured in accordance with Good Manufacturing Practices (cGMP) for bulk pharmaceutical chemicals.

[1] The use of AMBERLITE™ and DUOLITE™ pharmaceutical grade ion exchange resins as components of drug formulations is subject to the Food, Drug, and Cosmetic Act as amended.

## Typical Properties

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| **Physical Properties** | |
| Copolymer | Styrene-divinylbenzene |
| Type | Strong base anion |
| Functional Group | Quaternary amine |
| Physical Form | White to buff-colored, fine powder |
| **Chemical Properties** | |
| Ionic Form as Shipped | $Cl^-$ |
| Loss on drying [1] | 12.0% maximum |
| Identity (by IR spectrum) [1] | Identical to USP reference standard |
| Heavy metals [1][2] | 0.002% maximum |
| pH of slurry [1] | 4.1–6.0 |
| Residue on ignition [1] | 0.1% maximum |
| Dialyzable quaternary amine [1] | 0.05% |
| Chloride content [1] | 13.0–17.0% |
| Sodium glycocholate exchange capacity [1] | 1.8–2.2 g/g |
| Trimethylamine [1] | 20 ppm maximum |
| Organic volatile impurities <467>[1] | Meets requirements |
| **Particle Size** § | |
| < 150 microns | 95% minimum |
| < 75 microns | 65% minimum |
| < 45 microns | 45% maximum |

[1] Contractual value
[2] Appears in current USP/NF



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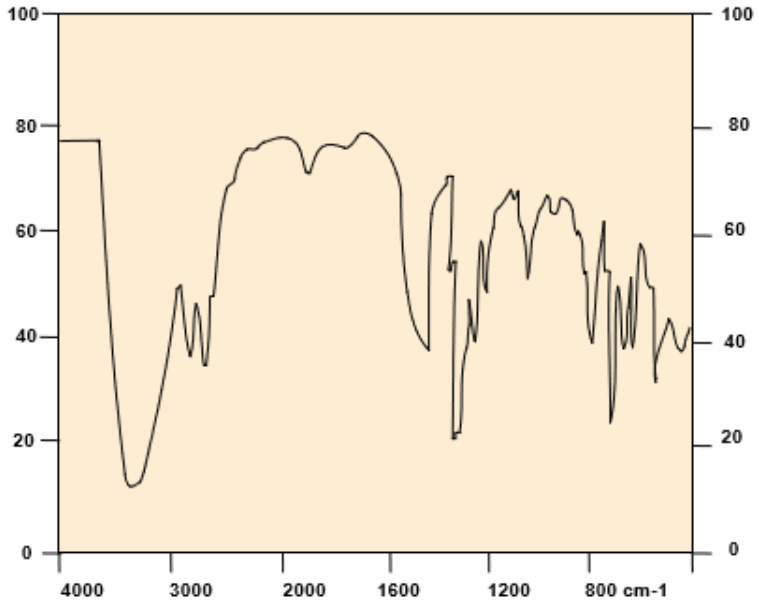
DUOLITE™ AP143/1073 complies with the compendial specifications for Cholestyramine Resin USP when tested in conformance to the compendial test methods presented in current USP/NF. The resin is described as a “White to buff colored, hygroscopic, fine powder. Is odorless or has not more than a slight amine-like odor. Insoluble in water, in alcohol, in chloroform and in ether.”

## Identification

DUOLITE™ AP143/1073 can be identified by infrared spectroscopy, as shown in the example Figure 1.

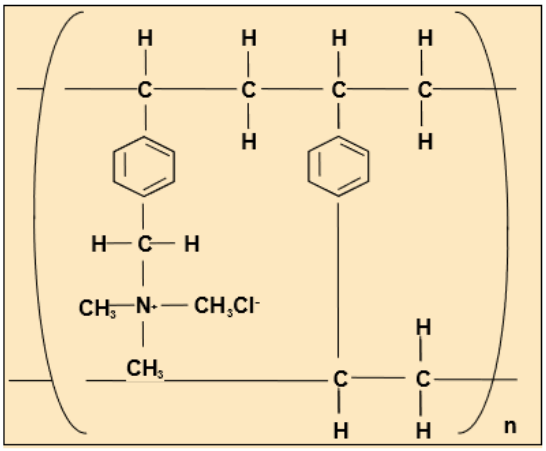
**Figure 1. DUOLITE™ AP143/1073 IR Spectrum**




## Chemical Properties

DUOLITE™ AP143/1073 is derived from a copolymer of styrene and divinylbenzene with quaternary ammonium functionality. The mobile, or exchangeable, anion is chloride which can be exchanged for, or replaced by, virtually any anionic species. DUOLITE™ AP143/1073 Resin is an insoluble salt of a strong base and a strong acid; hence, its ability to exchange anions is largely independent of pH. The chemical structure of DUOLITE™ AP143/1073 is shown below in Fig. 2.

**Figure 2. Chemical Structure**



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## Applications

- Taste Masking
- Drug Stabilization
- Controlled Release
- Active Ingredient

When used as a drug carrier, DUOLITE™ AP143/1073 provides a means for binding medicinal agents onto an insoluble polymeric matrix; this can be an effective technique to minimize taste and odor problems associated with the drug.

Controlled or sustained release properties can also be imparted to oral dosage formulations through the formation of resin-drug complexes (drug resinates). The drug is released from the resin in vivo as the drug resinate reaches equilibrium with the high electrolyte concentrations typically found in the gastrointestinal tract.

When used as an active ingredient, DUOLITE™ AP143/1073 resin binds bile acids; this leads to replenishment of the bile acids through increased catabolism of serum cholesterol, resulting in lowered serum cholesterol levels.

## Cholestyramine Applications Reference List


Irwin, W. J, R. MacHale, and P. J. Watts. (1990) Drug-delivery by ion exchange. Part VII: Release of acidic drugs from anionic exchange resinate complexes. Drug. Dev. Ind. Pharm. 16(6):883-898

Sriwongjanya, Mongkol; Bodmeier, Roland; Effect of ion exchange resins on the drug release from matrix tablets; College Pharmacy, Freie Universitaet Berlin, Berlin, D-12169, Germany; Eur. J. Pharm. Biopharm. (1998), 46(3), 321-327

Polli, Gerald P. and Shoop, Clyde E., (Merck and Co. USA), 1976. Palatable cholestyramine coacervate compositions. Patent US 3,974,272.

Brauns H. A., Polli, Gerald P and Shoop, Clyde E., (Merck and Co., USA), 1974. Cholestyramine containing coacervate. Ger. Offen DE 2,344,090.

Kunin, Robert; Blood cholesterol reducing pharmaceutical composition; 1998; Patent US 5840339.


## Product Stewardship

DuPont has a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our product stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with DuPont products—from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

## Customer Notice

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Please be aware of the following:

- **WARNING:** Oxidizing agents such as nitric acid attack organic ion exchange resins under certain conditions. This could lead to anything from slight resin degradation to a violent exothermic reaction (explosion). Before using strong oxidizing agents, consult sources knowledgeable in handling such materials.
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