

INDION[®] 454

(Cholestyramine Resin USP)

Description

INDION 454 is an insoluble, strongly basic anion exchange resin supplied as a dry, fine powder. INDION 454 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. INDION 454 conforms to the compendia specifications.

INDION 454 is derived from a co-polymer of Styrene and divinylbenzene, with quaternary ammonium functionality. The exchangeable anion is chloride which can be exchanged for, or replaced by virtually any anionic species. The parent material is manufactured in an ISO 9001 and ISO 14001 certified facility.

Application

When used as a drug carrier INDION 454 provides a means for binding medicinal agents onto an insoluble polymeric matrix; this can be an effective technique to minimise taste and odour problems associated with the drugs.

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

When used as an active ingredient, INDION 454 resin binds bile acids. This leads to replenishments of the bile acids through increased metabolism of serum cholesterol, resulting in lowered serum cholesterol levels.

Characteristics

Appearance	:	White to buff coloured powder
Matrix	:	Crosslinked styrene/DVB co-polymer
Functional Group	:	Quaternary ammonium
Ionic form as supplied	:	Chloride
Solubility	:	Insoluble in alcohol, chloroform and ether

Specifications

Identification		
By IR spectra	:	Identical to USP reference method
Particle size distribution		
Retained on 100 BSS mesh (150 microns)	:	1.0% maximum
Retained on 200 BSS mesh (75 microns)	:	45% maximum
Loss on drying	:	12%, maximum
pH of slurry	:	4.0 to 6.0
Sodium glycocholate exchange capacity	:	1.8 to 2.2 g/g
Residue on ignition	:	0.1%, maximum
Dialysable quaternary amine	:	0.05%
Chloride content	:	13.0 to 17.0%
Heavy metals content as Pb, ppm	:	20 maximum
Organic Volatile Impurities	:	Meets requirements

Toxicity

INDION 454 is a high molecular weight polymer. It is therefore not absorbed by body tissues and is totally safe for human consumption.

Packing

HDPE carboys with inner double plastic liner bag

6 / 20 / 40 kgs

Storage

INDION 454 is hygroscopic in nature. It is therefore essential to store it in a tightly packed container to prevent absorption of atmospheric moisture. If moisture is absorbed, the resin can be dried at 90° C to 100° C for approximately 6 hours to reduce the moisture content below 10%.

INDION range of Ion Exchange resins are produced in a state-of-the-art ISO 9001 and ISO 14001 certified manufacturing facilities at Ankleshwar, in the state of Gujarat in India.

To the best of our knowledge the information contained in this publication is accurate. Ion Exchange (India) Ltd. maintains a policy of continuous development and reserves the right to amend the information given herein without notice.

INDION is the registered trademark of Ion Exchange (India) Ltd.



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