

INDION® 254

Sodium Polystyrene Sulphonate

Description

INDION 254 is a high purity pharmaceutical grade strongly acidic cation exchange resin, supplied as a dry fine powder. It is suitable for use in pharmaceutical applications such as sustained release and taste masking of drugs. INDION 254 is derived from a sulphonated co-polymer of styrene and divinyl benzene. INDION 254 conforms to specifications of monograph for Sodium Polystyrene Sulphonate in USP/NF.

INDION 254 is manufactured in a FDA approved manufacturing facility. The parent material is manufactured in an ISO 9001 and ISO 14001 certified facility.

Applications

Taste masking of drugs

When used as a drug carrier INDION 254 provides a means for binding the active drug. This can afford an effective means for minimising the problem of taste and

odour which may be associated with the drug. The principle behind the technique of making a tasteless formulation with the help of INDION 254 is very simple and does not involve major capital investment. The complex is made from the drug and INDION 254. The nature of the complex is such that the average cation concentration of about 40 meq/l and pH of 6.7 in saliva is not able to break the complex. The complex is weak enough to be broken down by the hydrochloric acid present in the stomach. Thus, the complex is absolutely tasteless and stable with no after taste, but at the same time, its bio - availability is not affected.

Sustained release

Sustained release properties can also be imparted to oral dosage formulations through the formation of a complex using INDION 254. The drug is released from the resin in vivo as it reaches equilibrium with the high electrolyte concentration which is typical of the gastro - intestinal tract.

Characteristics

Appearance	:	Light cream to buff coloured powder
Matrix	:	Crosslinked polystyrene
Functional Group	:	Sulphonic acid
Ionic form as supplied	:	Sodium
Solubility	:	Insoluble in water and in common solvents

Specifications

Particle size distribution Retained on 100 BSS mesh (150 microns)	:	1.0%, maximum
Moisture content	:	10 %, maximum
Potassium exchange capacity	:	110 to 135 mg/dry g
Sodium content	:	9.4 to 11.5%
Iron content as Fe	:	100 ppm, maximum
Heavy metals content as Pb	:	20 ppm, maximum
Arsenic content as As	:	3 ppm, maximum
Ammonia	:	Passes USP XXII test

Toxicity

INDION 254 is a high molecular weight polymer. It is therefore not absorbed by body tissues and is totally safe for human consumption. Tests for toxicological tolerance show that it does not have any pronounced physiological action at recommended dosage level and is definitely non-toxic. Experiments on mice have shown that the LD50 values to be approximately 10,000 mg/kg body weight.

Packing

HDPE carboys with inner
double plastic liner bags

6 / 20 / 40 kgs

Storage

INDION 254 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, INDION 254 can be dried at 90° C to 100° C for approximately 6 hours to bring down 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. This product data sheet (issue 09/2008) replaces previous issues.

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



CORPORATE OFFICE

Tiecicon House, Dr. E. Moses Road, Mahalaxmi, Mumbai 400 011
Tel: 022-3989 0909 Fax: 022-2493 8737
E-mail: ieil@ionexchange.co.in ; hocro@ionexchange.co.in

INTERNATIONAL DIVISION

R-14, T.T.C MIDC, Thane-Belapur Road, Rabale, Navi Mumbai 400 705
Tel: 022-3989 0909/3047 2400 Fax: 022-2769 7918
E-mail: rabcrointl@ionexchange.co.in; export.sales@ionexchange.co.in

REGIONAL OFFICES

- **Chennai** - Tel: 044-3910 2900/ 3989 0909 Fax: 044-2815 3361
E-mail: checro@ionexchange.co.in
- **Delhi** - Tel: 011-3989 0909/3054 3200 Fax: 011-2577 4837
E-mail: delcro@ionexchange.co.in
- **Kolkata** - Tel: 033-3989 0909/3043 3400 Fax: 033-2400 4345
E-mail: calcro@ionexchange.co.in
- **Vashi** - Tel: 022-3989 0909/3913 2300 Fax: 022-2788 9839
E-mail: mumcro@ionexchange.co.in

BRANCH OFFICES

- **Bangalore** - Tel:-080-3251 6205, Cell:09341247700
E-mail: bngcro@ionexchange.co.in
- **Chandigarh** - Tel: 0172-274 5011 Fax: 0172-274 4594
E-mail: delcro@ionexchange.co.in
- **Hyderabad** - Tel: 040-3066 3101/02/03 Fax: 040-3066 3104
E-mail: hydcro@ionexchange.co.in
- **Lucknow** - Tel: 0522-301 3401/02 Fax: 0522- 301 3401
E-mail: luk.general@ionexchange.co.in
- **Pune** - Tel: 020-3062 6160 Fax: 020-2714 6109
E-mail: pun.general@ionexchange.co.in
- **Vadodara** - Tel: 0265-239 6506/6507 Fax: 0265-239 8508
E-mail: brdcro@ionexchange.co.in
- **Vizag** - Tel: 0891-324 6253
E-mail: sales.vizag@ionexchange.co.in

FACTORIES

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