

INDION® 204

Description

INDION 204 is a high purity pharmaceutical grade weak acid cation exchange resin, supplied in hydrogen form as a free flowing powder. It is suitable for pharmaceutical applications such as taste masking of bitter drugs. It is based on a cross linked polyacrylic matrix. INDION 204 is manufactured in a FDA approved manufacturing facility. The parent material is manufactured in an ISO 9001 and ISO 14001 certified facility.

A complex is made from the drug and INDION 204. 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.

Applications

INDION 204 is used for masking the bitter taste of drugs such as Roxithromycin, Norfloxacin and many others. It can be administered in a variety of dosage forms such as suspension, dispersible tablets, lozenges and chewing gums. The principle behind the technique of making a tasteless formulation is very simple and does not involve major capital investment.

Toxicity

INDION 204 is a high molecular weight cross linked polymer. It is therefore not absorbed by body tissue and is totally safe for human consumption. Tests for toxicological tolerance show that it does not have any pronounced physiological action at recommended dosage levels and is definitely non-toxic. Experiments on mice have shown LD 50 value of INDION 204 to be approximately 4,500 - mg/kg body weight.

Characteristics

| | | |
|------------------------|---|--|
| Appearance | : | White to pale cream powder |
| Matrix | : | Cross linked acrylic co - polymer |
| Functional Group | : | Carboxylic acid |
| Ionic form as supplied | : | Hydrogen |
| Solubility | : | Insoluble in water and in common solvents. |

Specifications

| | | |
|---|---|-----------------------|
| Particle size distribution | | |
| Retained on 100 BSS mesh (150 microns) | : | 1.0%, maximum |
| Retained on 200 BSS mesh (75 microns) | : | 45%, minimum |
| Moisture content | : | 5%, maximum |
| Total exchange capacity | : | 10 meq/dry g, minimum |
| Iron content as Fe | : | 100 ppm, maximum |
| Heavy metals content as Pb | : | 20 ppm, maximum |
| Arsenic content as As | : | 3 ppm, maximum |

Packing

HDPE carbouys with inner double plastic liner bags

6 / 20 / 40 kgs

Storage

INDION 204 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 204 can be dried at 90°C to 100°C for approximately six hours, to reduce the moisture content below 5%.

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



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