ION EXCHANGE
Refreshing the Planet

INDION® 234

Description

INDION 234 is a high purity pharmaceutical grade weak acid cation exchange resin supplied as a dry powder in potassium form. It is suitable for use in pharmaceutical applications for tablet disintegration and taste masking of bitter drugs. INDION 234 is based on crosslinked polyacrylic acid.

INDION 234 is manufactured in a FDA approved manufacturing facility. The parent material is manufactured in an ISO 9001 and ISO 14001 certified facility.

Applications

Tablet disintegration

INDION 234 is an effective tablet disintegrant which provides the necessary hardness and chemical stability to the tablet.
The product swells up considerably (about 300%) when in contact with water or gastro-intestinal fluids, causing rapid disintegration without the formation of lumps. Depending on the formulation, the use of 0.5% to 5% of INDION 234 is recommended for effective disintegration of the tablet. Some of the advantages of using INDION 234 as tablet disintegrant are:

- Remarkable swelling tendency on wetting, causing rapid disintegration.
- No lump formation on disintegration.
- Compatible with commonly used therapeutic agents and excipients.
- Works equally efficiently in hydrophilic and hydrophobic formulations.
- Gives good mechanical strength to the tablet, facilitating easy packing and transportation.
- Does not dissolve or have an adhesive tendency as in case of gums.
- Does not stick to punches and dyes.

Characteristics

Appearance	:	White to off white free flowing powder
Matrix	:	Crosslinked acrylic polymer
Functional Group	:	Carboxylic acid
Ionic form as supplied	:	Potassium
Solubility	:	Insoluble in water and in common solvents

Specifications

Particle size distribution Retained on 100 BSS mesh (150 microns)	:	1.0%, maximum
Passing through 200 BSS mesh (75 microns)	:	70%, minimum
Moisture content	:	10 %, maximum
Exchangeable potassium	:	5.25 meq/dry g, minimum
Potassium content	:	20.6 - 25.1%
Sodium content	:	0.2%, maximum
pH of 10% slurry	:	7.0 - 9.0
Iron content as Fe	:	100 ppm, maximum
Heavy metals content as Pb	:	20 ppm, maximum
Arsenic content as As	:	3 ppm, maximum

Taste masking agent

The principle behind the technique of making a formulation tasteless with the help of INDION 234 is very simple and does not involve major capital investment.The complex is made from the drug and INDION 234. 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.

The above technique has been found to be helpful in formulation of dosage forms such as dispersible tablets, chewable tablets, chewing gums and oral suspensions.

INDION 234 has proved to be an effective taste masking agent for the following drugs

- Chloroquine Phosphate
- Chloroquine Sulphate
- Ciprofloxacin Hydrobromide
- Lebexcin Hydrochloride
- Metclopramide Hydrochloride

Apart from these, use of INDION 234 is being considered as a taste masking agent for several other bitter drugs.

Toxicity

INDION 234 is a high molecular weight polymer. It isnot 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 and is definitely non- toxic. Experiments on mice have shown LD 50 value for INDION 234 to be approximately 10,000 mg/kg body weight.

Packing

HDPE carbouys with inner double plastic liner bags	6 / 20 / 40 kgs

Storage

INDION 234 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 INDION 234 can be dried at 90^0 C to 100^0 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.

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