Sodium Starch Glycolate

Carboxyméthylamidon sodique; Carboxymethylamylum natricum; Glicolato sódico de almidón; Karboksymetyloskrobia sodowa; Karboximetilkeményítő-nátrium; Karboxymethylškrob sodná sůl; Natriumstärkelseglykolat; Natriumtärkkelysglykolaatti; Sodium Carboxymethyl Starch; Sodium Starch Glycollate; Starch Sodium Glycolate.

CAS — 9063-38-1.

Pharmacopoeias. In *Chin.* and *Eur.* (see p.vii). Also in *USNF.*

Ph. Eur. 6.2 (Sodium Starch Glycolate (Type A); Carboxymethylamylum Natricum A). The sodium salt of a cross-linked partly *O*-carboxymethylated potato starch. It contains 2.8 to 4.2% of sodium, calculated with reference to the substance washed with alcohol (80%) and dried. A fine, white or almost white, very hygroscopic, free-flowing powder. It forms a translucent suspension in water; practically insoluble in dichloromethane. pH of a 3.33% dispersion in water is 5.5 to 7.5. Store in airtight containers. Protect from light.

Ph. Eur. 6.2 (Sodium Starch Glycolate (Type B); Carboxymethylamylum Natricum B). The sodium salt of a cross-linked partly *O*-carboxymethylated potato starch. It contains 2.0 to 3.4% of sodium, calculated with reference to the substance washed with alcohol (80%) and dried. A fine, white or almost white, very hygroscopic, free-flowing powder. It forms a translucent suspension in water; practically insoluble in dichloromethane. pH of a 3.33% dispersion in water is 3.0 to 5.0. Store in airtight containers. Protect from light.

Ph. Eur. 6.2 (Sodium Starch Glycolate (Type C); Carboxymethylamylum Natricum C). The sodium salt of a cross-linked by physical dehydration, partly *O*-carboxymethylated starch. It contains 2.8 to 5.0% of sodium, calculated with reference to the substance washed with alcohol (80%) and dried. A fine, white or almost white, very hygroscopic, free-flowing powder. It forms a translucent gel-like product in water; practically insoluble in dichloromethane. pH of a 3.33% gel in water is 5.5 to 7.5. Store in airtight containers. Protect from light.

USNF 26 (Sodium Starch Glycolate). The sodium salt of a carboxymethyl ether of starch or of a cross-linked carboxymethyl ether of starch. It may contain not more than 7.0% of sodium chloride. The sodium content is 2.8 to 4.2% (Type A) or 2.0 to 3.4% (Type B). pH of a 1 g in 30 mL suspension in water is between 5.5 and 7.5 (Type A) or between 3.0 and 5.0 (Type B).

A white, odourless, relatively free-flowing powder available in several different viscosity grades. A 2% dispersion in cold water settles, on standing, in the form of a highly hydrated layer. Protect from wide variations in temperature and humidity which may cause caking.

Uses

Sodium starch glycolate is used as a disintegrating agent in tablet manufacture.

Tragacanth

Dragant; E413; Goma Alcatira; Goma de tragacanto; Gomme adragante; Gum Dragon; Gum Tragacanth; Trag.; Tragacanta; Tragacantha; Tragacanto; Tragakanta; Tragakantas; Tragant; Tragantti.

CAS — 9000-65-1.

Pharmacopoeias. In *Eur.* (see p.vii) and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Tragacanth). The air-hardened gummy exudation flowing naturally or obtained by incision from the trunk and branches of *Astragalus gummifer* and some other species of *Astragalus* (Leguminosae) from western Asia. It occurs as thin, flattened, ribbon-like, white or pale yellow, translucent, horny strips. When reduced to a powder it forms a mucilaginous gel with about ten times its weight of water. Protect from light.

USNF 26 (Tragacanth). The dried gummy exudation from *Astragalus gummifer* or other Asiatic species of *Astragalus* (Leguminosae). It occurs as odourless, flattened, lamellated, frequently curved fragments or straight or spirally twisted linear pieces. It is white to weak yellow, translucent, and horny in texture. Powdered tragacanth is white to yellowish-white.

Adverse Effects

Hypersensitivity reactions, sometimes severe, have occurred rarely after the ingestion of products containing tragacanth. Contact dermatitis has been reported following the external use of tragacanth.

Uses

Tragacanth forms viscous solutions or gels with water, depending on the concentration. It is used in pharmaceutical manufacturing as a suspending agent and as an emulsifying agent. In dispensing aqueous preparations of tragacanth, the powdered tragacanth is first dispersed in a wetting agent, such as alcohol, to prevent agglomeration on the addition of water.

Tragacanth is also used for similar purposes in the food industry.

Xanthan Gum

Corn Sugar Gum; E415; Goma de xantána; Gomme xanthane; Ksantaanikumi; Ksantano lipai; Polysaccharide B 1459; Xantán gumi; Xantangummi; Xantham Gum; Xanthani gummi; Xanthanová klovatina.

CAS — 11138-66-2.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*

Ph. Eur. 6.2 (Xanthan Gum). A gum produced by fermentation of a carbohydrate with *Xanthomonas campestris* and purified. It is the sodium, potassium, or calcium salt of a high-molecular-weight polysaccharide containing D-glucose, mannose, and glucuronic acid. It also contains not less than 1.5% of pyruvic acid, calculated with reference to the dried substance. A white or yellowish-white, free-flowing powder. Soluble in water giving a highly viscous solution; practically insoluble in organic solvents. A 1% solution in water has a pH of 6.0 to 8.0.

USNF 26 (Xanthan Gum). A high-molecular-weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris* and purified. It contains D-glucose, D-mannose, and D-glucuronic acid. It is prepared as the sodium, potassium, or calcium salt. A cream-coloured powder. Soluble in hot or cold water. Its solutions are neutral to litmus.

Uses

Xanthan gum is used in pharmaceutical manufacturing as a suspending, stabilising, thickening, and emulsifying agent. It is also used similarly in the food industry.

◊ Suspensions of crushed tablets or insoluble powders made with xanthan gum were reported to be preferable to those made with tragacanth.[1]

The stability was generally good and only a small number of drugs had been found to be incompatible (amitriptyline, tamoxifen, and verapamil).[1] For extemporaneous dispensing, a 1% solution of xanthan gum with hydroxybenzoate, prepared in advance, was diluted to 0.5% with water when preparing the suspension.

Xanthan gum was found to be a suitable suspending vehicle for delivering antispasmodics topically along the length of the oesophagus in patients with oesophageal spasm.[2] Coagulation of the gum had been observed when it was used for suspensions of certain film-coated tablets.

1. Anonymous. "Extremely useful" new suspending agent. *Pharm J* 1986; **237:** 665.
2. Evans BK, Fenton-May V. Keltrol. *Pharm J* 1986; **237:** 736–7.

Preparations

USNF 26: Xanthan Gum Solution.

Proprietary Preparations (details are given in Part 3)
Ger.: Ronfnyl; ***Malaysia:*** Ronfnyl†; ***Switz.:*** TenderWet†.

Multi-ingredient: ***Ital.:*** Resource Gelificata.