Isomalt

1 Nonproprietary Names

BP: Isomalt
PhEur: Isomalt
USP–NF: Isomalt

2 Synonyms

*C*PharmIsoMaltidex*; E953; *galenIQ*; hydrogenated isomaltulose; hydrogenated palatinose; *IsoMaltidex 16500*; isomaltum; *Palatinit*.

3 Chemical Name and CAS Registry Number

Isomalt [64519-82-0]

Isomalt is a mixture of two stereoisomers:

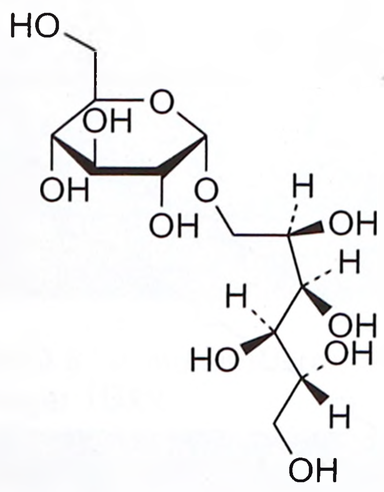
6-*O*-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) [534-73-6]

1-*O*-α-D-glucopyranosyl-D-mannitol dihydrate (1,1-GPM) [20942-99-8]

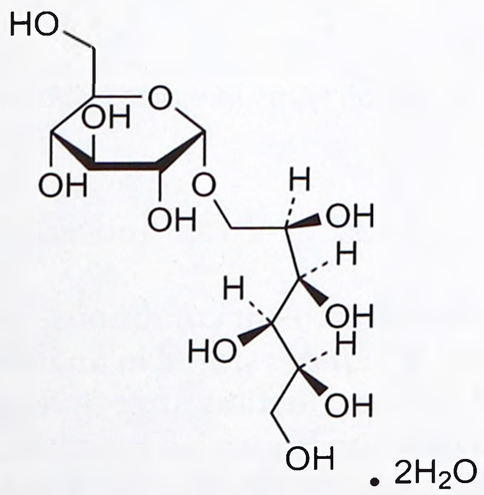
4 Empirical Formula and Molecular Weight

$C_{12}H_{24}O_{11}$ 344.32 (for anhydrous)
$C_{12}H_{24}O_{11}\cdot 2H_2O$ 380.32 (for dihydrate)

5 Structural Formula



$C_{12}H_{24}O_{11}$
(1,6-GPS)



$C_{12}H_{24}O_{11}\cdot 2H_2O$
(1,1-GPM)

Generally, isomalt comprises a mixture of 1,6-GPS and 1,1-GPM. 1,6-GPS crystallizes without water and is more soluble than 1,1-GPM. By shifting the ratio of the two components, the solubility and crystal water content can be adjusted; *see* Section 10. *GalenIQ 720* has a GPM : GPS ratio of 1 : 1; *galenIQ 721* has a GPM : GPS ratio of 1 : 3.

6 Functional Category

Coating agent; direct compression excipient; suspending agent; sweetening agent; tablet and capsule binder; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Isomalt is a noncariogenic excipient used in a variety of pharmaceutical preparations including tablets or capsules, in coatings as a sugar-free coating agent, sachets, dry powder for suspension, and in effervescent tablets. It can also be used in direct compression, roller compaction, and wet granulation.[1]

In buccal applications such as chewable tablets it is commonly used because of its negligible negative heat of solution, mild sweetness, and 'mouth feel'.[2,3] It is also used widely in medicated high-boiled lozenges such as cough drops, as a sweetening agent in medicated confectionery for diabetics, and in sugar-free chewing gum.

See also Section 18.

8 Description

Isomalt is a sugar alcohol (polyol) that occurs as a white or almost white powder or granular or crystalline substance. It has a pleasant sugar-like taste with a mild sweetness approximately 50–60% of that of sucrose.[2–4]

9 Pharmacopeial Specifications

The pharmacopeial specifications for isomalt have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table I.

Table I: Pharmacopeial specifications for isomalt.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters[a]	+	—
Organic impurities	+	+
Conductivity	≤20 µS cm^{-1}	≤20 µS cm^{-1}
Reducing sugars	≤0.3%	≤0.3%
Heavy metals	—	≤10 µg/g
Nickel	≤1 ppm	≤1 µg/g
Water	≤7.0%	≤7.0%
Assay	98.0–102.0%	98.0–102.0%

(a) This test has not been fully harmonized at the time of publication.

10 Typical Properties

Angle of repose *see* Table II.

Compressibility Compression characteristics may vary, depending on the grade of isomalt used; *see* Figure 1.

Density (bulk) *see* Table II.

Density (tapped) *see* Table II.

Density (true)

1.52 g/cm^3 for 1,6-GPS;

1.47 g/cm^3 for 1,1-GPM.

Flowability Powder is cohesive; granules are free flowing.[2]

Glass transition temperature

63°C for a 1 : 3 mixture of 1,1-GPM and 1,6-GPS;