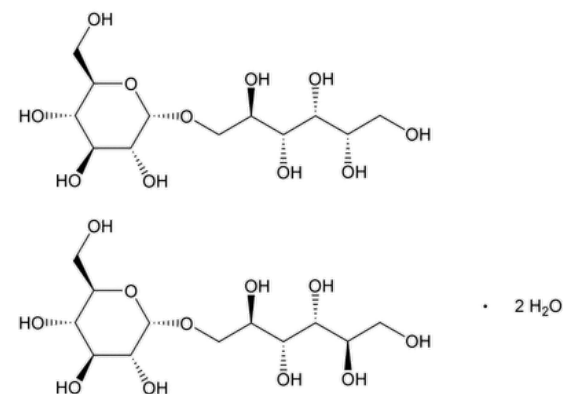


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Isomalt

Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (†) to specify this fact.



$C_{12}H_{24}O_{11}$ 344.31

$C_{12}H_{24}O_{11} \cdot 2H_2O$ 380.32

6-O-α-D-Glucopyranosyl-D-sorbitol and 1-O-α-D-glucopyranosyl-D-mannitol dihydrate;

6-O-α-D-Glucopyranosyl-D-glucitol and 1-O-α-D-glucopyranosyl-D-mannitol dihydrate CAS RN®: 64519-82-0.

DEFINITION

Isomalt contains NLT 98.0% and NMT 102.0% of a mixture of 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-α-D-glucopyranosyl-D-mannitol (1,1-GPM), and neither of the two components is less than 3.0% of the mixture, calculated on the anhydrous basis.

IDENTIFICATION

† A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Standard solution: 5 mg/mL of [USP Isomalt RS](#)

Sample solution: 5 mg/mL

Chromatographic system

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture containing a fluorescent indicator having optimal intensity at 254 nm

Application volume: 1 µL

Developing solvent system: [Ethyl acetate](#), [pyridine](#), water, [acetic acid](#), and [propionic acid](#) (10:10:2:1:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Thoroughly dry the starting points in warm air. Develop over 10 cm using the *Developing solvent system*, dry the plate in a current of hot air, and dip for 3 s in a 1-mg/mL solution of [sodium periodate](#). Dip the plate for 3 s in a mixture of [dehydrated alcohol](#), [sulfuric acid](#), [acetic acid](#), and [anisaldehyde](#) (90:5:1:1). Dry the plate in a current of hot air until colored spots become visible. The background color may be brightened by exposure to warm steam. Examine in daylight.

Acceptance criteria: The principal spots of the *Sample solution* are similar in position and color to those of the *Standard solution*.

† B. The retention times of the two principal peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

† PROCEDURE

Mobile phase: Water

Standard solution: 20 mg/mL of [USP Isomalt RS](#)

Sample solution: 20 mg/mL of Isomalt

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: Refractive index, maintained at a constant temperature (40° for example)

Columns

Guard: 4.6-mm × 3-cm; packing L19

Analytical: 7.8-mm × 30-cm; packing L19

Column temperature: 80 ± 3°

Flow rate: 0.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for 1,1-GPM and 1,6-GPS are about 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between 1,1-GPM and 1,6-GPS

Relative standard deviation: NMT 2.0% for the 1,6-GPS and 1,1-GPM peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 1,6-GPS in the portion of Isomalt taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of 1,6-GPS from the *Sample solution*

r_S = peak response of 1,6-GPS from the *Standard solution*

C_S = concentration of 1,6-GPS in the *Standard solution*, with calculation based on the declared 1,6-GPS content of [USP Isomalt RS](#) (mg/mL)

C_U = concentration of Isomalt in the *Sample solution* (mg/mL)

Calculate the percentage of 1,1-GPM in the portion of Isomalt taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of 1,1-GPM from the *Sample solution*

r_S = peak response of 1,1-GPM from the *Standard solution*

C_S = concentration of 1,1-GPM in the *Standard solution*, with calculation based on the declared 1,1-GPM content of [USP Isomalt RS](#) (mg/mL)

C_U = concentration of Isomalt in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% of a mixture of 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-α-D-glucopyranosyl-D-mannitol (1,1-GPM), and neither of the two components is less than 3.0% of the mixture, calculated on the anhydrous basis

IMPURITIES

• **LIMIT OF NICKEL**

[NOTE—The purity of the reagents and the water used must be suitable for trace analysis, and the reagents and water must be free of nickel.]

Sample solution: Dissolve 10.0 g of Isomalt in 30 mL of dilute acetic acid (115–125 g/L), add water, and shake to dissolve. Dilute with water to 100.0 mL. Add 2.0 mL of [saturated ammonium pyrrolidinedithiocarbamate TS](#) and 10.0 mL of water-saturated [methyl isobutyl ketone](#) (C₆H₁₂O, 4-methyl-2-pentanone), and then shake for 30 s, protected from bright light. Allow the layers to separate and use the methyl isobutyl ketone layer.

Standard solutions: Prepare three reference solutions in the same manner as the *Sample solution* except add 0.5 mL, 1.0 mL, and 1.5 mL, respectively, of [nickel standard solution TS](#) (10 ppm Ni) in addition to the 10.0 g of the substance to be examined.

Blank solution: Treat water-saturated [methyl isobutyl ketone](#) as described for preparation of the *Sample solution* omitting the Isomalt.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)