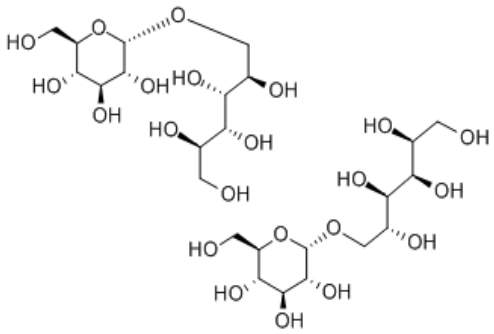
United States Pharmacopeia

Isomalt



CAS No.	64519-82-0
Chemical Name:	Isomalt
CB Number:	CB1309643
Molecular Formula:	C12H24O11
Formula Weight:	344.31

Cs = concentration of 1, 6-GPS or 1, 1-GPM in the Standard solution (mg/ml) [Calculated Based on the declared 1, 6-GPS or 1, 1-GPM Content of USP lsomalt RS]
Cu = concentration of sample in the Sample Solution (mg/ml)

Calculate the percentage of total hydrogenated mono and disaccharides (%THS) in the sample taken using
The following equation:

%THS =A+ B

A = sum of the percentages of 1, 6-GPS and 1, 1 GPM in the sample taken calculated above
B = sum of the percentages of mannitol and Sorbitol in the sample, determined separately in the Mannitol and Sorbitol test procedure below
Acceptance criteria: NLT 98.0% of total hydrogenated Mono- and disaccharides (%THS) and NLT 86% of the Mixture of 1, 6-GPS and 1, 1-GPM, calculated on the Anhydrous basis.

IMPURITIES
Inorganic Impurities
• **LEAD**, Lead Limit Test, Atomic Absorption Spectrophotometric
Graphite Furnace Method, Method I, Appendix IIIB
Acceptance criteria: NMT 1 mg/kg
• **NICKEL**, Nickel Limit Test, Method II, Appendix IIIB
Acceptance criteria: NMT 2 mg/kg

Organic Impurities
• MANNITOL AND SORBITOL
Mobile phase: Degassed water
Standard solution: 0.1 mg/ml each of USP Sorbitol RS and USP Mannitol RS
System suitability solution: 20 mg/ml, 0.1 mg/ml, and 0.1 mg/ml of USP lsomalt RS, USP Sorbitol RS, and USP Mannitol RS, respectively
Sample solution: 20 mg/ml
Chromatographic system, Appendix IIA
Mode: High-performance liquid chromatography
Detector: Refractive index
Column: 7.8-mm x 30-cm analytical column 1 and a 4.6-mm x 3-cm guard column, both packed with a strong cation-exchange resin consisting of sulfonated cross-linked styrene-divinylbenzene copolymer in the calcium form, about 9 µm in diameter
Column temperature: 80 ± 1°
Flow rate: About 0.5 ml/min
Injection volume: About 20 µL
System suitability
Sample: System suitability solution
Resolution: NLT 2.0 between 1, 1-GPM and 1, 6-GPS
Analysis: Separately inject equal volumes of the Standard solution and Sample solution into the chromatograph, record the chromatograms, and measure the responses for the for 1, 6-GPS and 1,

1 GPM. [NOTE-The typical retention time of 1, 1-GPM is about 12.3 min; the relative retention times are about 1.2 for 1 ,6-GPS, about 1.6 for mannitol, about 2.0 for sorbitol, and 1.0 for 1, 1-GPM.]

Separately calculate the percentages of mannitol and sorbitol in the sample taken by the following formula:

$$\textbf{Result} = (r_u/r_s) * (C_s/C_u) * 100\%$$

r_u = peak response for mannitol or sorbitol from the Sample solution

r_s = peak response for mannitol or sorbitol from the Standard solution

C_S = concentration of mannitol or sorbitol in the Standard solution (mg/ml)

C_u = concentration of sample in the Sample solution (mg/ml)

Acceptance criteria: NMT 3% mannitol and NMT 6% sorbitol

• REDUCING SUGARS

Alkaline tartrate solution: Dissolve 34.6 g of potassium sodium tartrate (Rochelle salt) and 1 0 g of sodium hydroxide in water, dilute to 100 ml, let stand 2 days, and filter through glass wool.

Sample: 7 g

Analysis: Dissolve the Sample in 35 ml of water in a 400-ml beaker, and mix. Add 25 ml of cupric sulfate TS and 25 ml of Alkaline Tartrate Solution. Cover the beaker with glass and heat the mixture at such a rate that it comes to a boil in approximately 4 min and boils for exactly 2 min. Filter the precipitated cuprous oxide through a tared Gooch crucible previously washed with hot water, ethanol, and ether, and dried at 1ooo for 30 min. Thoroughly wash the collected cuprous oxide on the filter with hot water, then with 10 ml of ethanol, and finally with 10 ml of ether, and dry at 1ooofor 30 min. Weigh the filter containing the cuprous oxide.

Acceptance criteria: The weight of the cuprous oxide does not exceed 50 mg (NMT 0.3% (as glucose)).

SPECIFIC TESTS

• WATER, Water Determination, Appendix llB

Acceptance criteria: NMT 7.0%

• RESIDUE ON IGNITION (SULFATED ASH), Appendix IIC

Sample: 5 g

Acceptance criteria: NMT 0.05%