MALTITOL SYRUP

Prepared at the 49th JECFA (1997), published in FNP 52 Add 5 (1997) superseding specifications prepared at the 46th JECFA (1996), published in FNP 52 Add 4 (1996). An ADI 'not specified' was established at the 49th JECFA (1997)

SYNONYMS Hydrogenated high maltose-content glucose syrup, hydrogenated glucose syrup, dried maltitol syrup, maltitol syrup powder
INS No. 965(ii)

DEFINITION A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup. The article of commerce is typically supplied as a syrup. It may also be dried and supplied as a solid product

Assay Not less than 99.0% of total hydrogenated saccharides on the anhydrous basis and not less than 50.0% of maltitol on the anhydrous basis

DESCRIPTION Colourless and odourless, clear viscous liquids or white crystalline masses

FUNCTIONAL USES Sweetener, humectant, texturizer, stabilizer, bulking agent

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Very soluble in water, slightly soluble in ethanol

Thin layer chromatography (Vol. 4) Passes test
Proceed as directed under *Thin Layer Chromatography of Polyols*

Standard solution
Dissolve 50 mg of reference standard maltitol (available from US Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, USA) in 20 ml water

Test solution
Dissolve 50 mg of sample in 20 ml of water

PURITY

Water (Vol. 4) Not more than 31% (Karl Fischer)

Sulfated ash (Vol. 4) Not more than 0.1 %
Test 3 g of the sample (Method I)

Chloride (Vol. 4)

Not more than 50 mg/kg
Test 10 g of the sample by the Limit Test using 1.5 ml of 0.01 N hydrochloric acid in the standard

Sulfate (Vol. 4)

Not more than 100 mg/kg
Test 10 g of the sample by the Limit Test using 2.0 ml of 0.0l N sulfuric acid in the standard

Nickel (Vol. 4)

Not more than 2 mg/kg
Proceed as directed under *Nickel in Polyols*

Reducing sugars (Vol. 4)

Not more than 0.3%
Proceed as described under *Reducing Substances (as glucose)*, Method II. The weight of cuprous oxide shall not exceed 50 mg

Lead (Vol. 4)

Not more than 1 mg/kg
Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."

METHOD OF ASSAY

Total hydrogenated saccharides (%)

$$\frac{100 - (\text{Water\%} + \text{Sulfated ash\%} + \text{Reducing sugars\%})}{100 - \text{Water\%}} \times 100$$

Determine the maltitol content using liquid chromatography.

Apparatus
-Detection: Differential refractometer maintained at constant temperature
-Integrator recorder
-Liquid chromatograph (HPLC)
-Column: AMINEX HPX 87 C (resin in calcium form), length 30 cm, internal diameter 9 mm
-Eluent: Double distilled degassed water (filtered through Millipore membrane filter 0.45 µm)

Chromatographic conditions
Column temperature: 85 ± 0.5°
Eluent flow rate: 0.5 ml/min

Standard preparation
Dissolve an accurately weighed quantity of standard reference maltitol (available from US Pharmacopeial Convention Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, USA) in water to obtain a solution having known concentration of about 10.0 mg of maltitol per ml.

Sample preparation
Transfer about 1 g of the sample accurately weighed to a 50-ml volumetric flask, dilute with water to volume and mix.

Procedure

Separately inject equal volumes (about 20 µl) of the sample preparation and the standard preparation into the chromatograph. Record the chromatograms and measure the responses of each maltitol peak. Calculate the quantity, in mg, of maltitol in the syrup by the following formula:

$$50 \times C \times \frac{R_U}{R_S}$$

where

C = the concentration, in mg per ml, of maltitol in the standard preparation

R_U = the peak response of the sample preparation

R_S = the peak response of the standard preparation