POLYGLYCITOL SYRUP

Prepared at the 51st JECFA (1998) and published in FNP 52 Add 6 (1998). Group ADI "not specified" for polyglycitol and maltitol syrups, established at the 51st JECFA in 1998.

SYNONYMS Hydrogenated starch hydrolysate, polyglucitol

DEFINITION A mixture consisting mainly of maltitol and sorbitol and lesser amounts of hydrogenated oligo and polysaccharides and maltrotriitol. Manufactured by the catalytic hydrogenation of a mixture consisting of glucose, maltose, and higher glucose polymers; typically supplied as a syrup; 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 more than 50.0% of maltitol and not more than 20.0% of sorbitol 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

Test for maltitol
Passes test for maltitol
as directed under *Thin Layer Chromatography of Polyols*
Use the following:
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 the sample in 20 ml of water

Test for sorbitol To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde, and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter the crystals and dissolve in 20 ml of boiling water containing 1 g of sodium bicarbonate. Filter the hot solution and allow to cool until crystals are formed. Filter the crystals, wash with 5 ml of a water-methanol mixture (1 in 2), and dry in air. The crystals of the monobenzylidine derivative of sorbitol so obtained melt between 173 and 179º.

PURITY

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

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

Chlorides (Vol. 4) Not more than 50 mg/kg
Test 10 g of sample by the Limit Test using 1.5 ml of 0.01N hydrochloric acid in the control

Sulfates (Vol. 4)

Not more than 100 mg/kg
Test 10 g of sample by the Limit Test using 2.0 ml of 0.01N sulfuric acid in the control

Nickel (Vol. 4)

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

Reducing sugars

Not more than 0.3%
Proceed as directed 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 and sorbitol content using liquid chromatography.

Apparatus
Liquid chromatograph (HPLC)
- Detection: Differential refractometer maintained at constant temperature
- Integrator recorder
- Column: AMINEX HPX 87 C or equivalent, (resin in calcium form), length 30 cm, internal diameter 9 mm
- Eluent: Double distilled degassed water (filtered through Millipore membrane filter or equivalent, 0.45 µm)
Chromatographic conditions
Column temperature: 85±0.5°
Eluent flow rate: 0.5 ml/min

Standard preparation:
Dissolve accurately weighed quantities of standard reference maltitol and sorbitol (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 and 5.0 mg of sorbitol 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. Filter through a 0.2 micron filter.

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 polyol (maltitol,

sorbitol) peak. Calculate separately the quantities, in mg, of maltitol and sorbitol in the portion of syrup taken by the following formula:

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

where
C = the concentration, in mg per ml, of the corresponding polyol in the standard preparation
R_U = the peak response of the polyol in the sample preparation
R_S = the peak response of the corresponding polyol in the standard preparation.