SORBITOL SYRUP

Prepared at the 46th JECFA (1996), published in FNP 52 Add 4 (1996) superseding specifications prepared at the 33rd JECFA (1988), published in FNP 38 (1988) and in FNP 52 (1992). Metals and arsenic specifications revised at the 57th JECFA (2001). No ADI was allocated at the 33rd JECFA (1988)

SYNONYMS D-Glucitol syrup, INS No. 420(ii)

DEFINITION Formed by hydrogenation of glucose syrup; composed of D-sorbitol, D-mannitol and other hydrogenated saccharides
The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallizing) or mannitol; minor quantities of hydrogenated di-, tri- and tetrasaccharides may be present

Assay — Not less than 99.0% hydrogenated saccharides and not less than 50.0% of D-sorbitol on the anhydrous basis

DESCRIPTION Clear colourless aqueous solution

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

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) — Soluble in water, glycerol and propan-1,2-diol

Thin layer chromatography (Vol. 4) — Passes test
Proceed as directed under *Thin Layer Chromatography of Polyols*
Use the following:

Standard solution:
Dissolve 50 mg of reference standard sorbitol (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

PURITY

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

Sulfated ash (Vol. 4) — Not more than 0.1%
Test 3 g of 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 (%):

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

Determine the sorbitol content of the sample 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 0.45 µm)

Chromatographic conditions
Column temperature: 85±0.5^{o}
Eluent flow rate: 0.5 ml/min

Standard preparation
Dissolve an accurately weighed quantity of sorbitol in water to obtain a solution having known concentration of about 10.0 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.

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 peak. Calculate separately the quantity, in mg, of sorbitol in the portion of sample taken by the following formula:

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

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