LACTITOL

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). Metals and arsenic specifications revised at the 57th JECFA (2001), An ADI 'not specified' was established at the 27th JECFA (1983)

SYNONYMS Lactit, lactositol, lactobiosit, INS No. 966

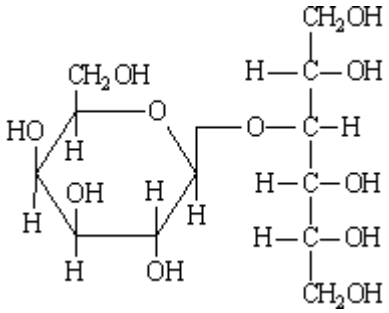
DEFINITION

Chemical names 4-O-ß-D-Galactopyranosyl-D-glucitol

C.A.S. number 585-86-4

Chemical formula $C_{12}H_{24}O_{11}$

Structural formula



Formula weight 344.32

Assay Not less than 95.0% and not more than 102.0% on the anhydrous basis

DESCRIPTION Sweet tasting crystalline powders or colourless solutions; crystalline products occur in both monohydrate and dihydrate forms

FUNCTIONAL USES Sweetener, texturiser

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Very soluble in water

Specific rotation (Vol. 4) [alpha] 25, D: Between +13 and +15º (10% w/v aqueous solution)

Main peak in HPLC The main HPLC peak exhibited by the sample in the assay has the same elution time as that of the lactitol standard
See Method of Assay

PURITY

Water (Vol. 4) Crystalline products: Not more than 10.5% (Karl Fischer Method)
Solutions: Not more than 31% (Karl Fischer Method)

Sulfated ash (Vol. 4)	Not more than 0.1% on the anhydrous basis Test 2 g (anhydrous basis) (Method I)
Chlorides (Vol. 4)	Not more than 100 mg/kg on the anhydrous basis Test an amount of sample equivalent to 10 g of the anhydrous substance by the Limit Test using 3.0 ml of 0.01N hydrochloric acid in the standard
Sulfates (Vol. 4)	Not more than 200 mg/kg on the anhydrous basis Test an amount of sample equivalent to 10 g of the anhydrous substance by the Limit Test using 4.0 ml of 0.01N sulfuric acid in the standard
Other polyols	Not more than 2.5% on the anhydrous basis See Method of Assay
Reducing sugars	Not more than 0.1% Proceed as directed under *Reducing Substances (as glucose),* Method II. The weight of cuprous oxide shall not exceed 20 mg.
Nickel	Not more than 2 mg/kg See description under TESTS
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.”

TESTS

PURITY TESTS

Nickel

Test solution

Dissolve 20.0 g of the substance to be examined in a mixture of equal volumes of dilute acetic acid TS* and water and dilute to 100 ml with the same mixture of solvents. Add 2.0 ml of a 1% w/v solution of ammonium pyrrolidinedithiocarbamate and 10 ml of methyl isobutyl ketone. Mix and allow the layers to separate and use the methyl isobutyl ketone layer.

Standard solution

Prepare three standard solutions in the same manner as the test solution but adding 0.5 ml, 1.0 ml, and 1.5 ml, respectively, of a standard nickel solution containing 10 mg/kg Ni, in addition to the 20.0 g of the sample.

Procedure

Set the instrument to zero using methyl isobutyl ketone as described for the preparation of the test solution but omitting the substance to be examined. Measure the absorbance at 232.0 nm using a nickel hollow-cathode lamp as source of radiation and an air-acetylene flame.

METHOD OF

Principle

ASSAY

Determine lactitol as well as other polyols resulting as by-products during the manufacture of lactitol by *liquid chromatography*. Principal by-product polyols are the hexitols: sorbitol, mannitol, galactitol (dulcitol), and lower polyols such as glycitols.

Apparatus
Liquid chromatograph with elevated temperature capability, differential refractometric detector and 0.45 µm membrane filter before column.

Column
Aminex HPX 87 (calcium form) with dimensions 300 x 7.8 mm, or equivalent column designed for carbohydrate analyses

Standards
Lactitol, sorbitol, mannitol

Eluent
Water (degassed)

Procedure
Equilibrate chromatography column to 85º. Adjust eluent flow rate through column to 0.6 ml/min. Accurately prepare an aqueous solution of sample about 40% by weight. Inject 10 µl of the 40% sample solution onto the column. Record the chromatogram for peaks occurring at the retention time of lactitol and thereafter.

Approximate retention times for lactitol and other polyols using the recommended column are:

Lactitol 12 min
Ribitol 15 min
Erythritol 16 min
Mannitol 18 min
Galactitol 20 min
Sorbitol 21 min

For Assay, compare the sample response relative to the response of a standard sample of lactitol of known purity.

For other polyols, measure the area of all peaks occurring between Lactitol and Sorbitol. The sum of the areas of these peaks is not greater than 2.5 % of the dry weight of the sample.