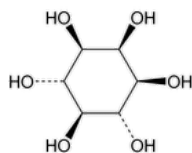


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Inositol



$C_6H_{12}O_6$ 180.16

cis-1,2,3,5-*trans*-4,6-Cyclohexanehexol;

myo-Inositol CAS RN®: 87-89-8.

DEFINITION

Inositol contains NLT 97.0% and NMT 102.0% of Inositol ($C_6H_{12}O_6$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Water

System suitability solution: 0.05 mg/mL of [USP Inositol RS](#) and 0.05 mg/mL of [USP Mannitol RS](#)

Standard solution: 50 mg/mL of [USP Inositol RS](#)

Sample solution: 50 mg/mL of Inositol

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm or equivalent; packing L19

Temperature

Column: 85°

Detector: Constant temperature of 30°–35°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for inositol and mannitol are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 4.0 between inositol and mannitol, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—Record the chromatograms over a period of two times the retention time of inositol, and measure the peak responses.]

Calculate the percentage of Inositol ($C_6H_{12}O_6$) in the portion of sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of inositol from the *Sample solution*

r_S = peak response of inositol from the *Standard solution*

C_S = concentration of [USP Inositol RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Inositol in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

• BARIUM

Sample solution: Use the *Sample solution* prepared in the test for *Clarity of Solution*. To 10 mL of the *Sample solution* add 1 mL of diluted sulfuric acid.

Acceptance criteria: When examined immediately and after 1 h, any opalescence in the solution is not more intense than that in a mixture of 1 mL of water and 10 mL of the *Sample solution* from the test for *Clarity of Solution*.

Change to read:

• LIMIT OF LEAD

Lead nitrate stock solution: Dissolve 159.8 mg of lead nitrate in 100 mL of water to which has been added 1 mL of nitric acid, then dilute with water to 1000 mL. Prepare and store this solution in glass containers free from soluble lead salts.

Standard lead solution: On the day of use, dilute 10.0 mL of the *Lead nitrate stock solution* with water to 100.0 mL. Each mL of the *Standard lead solution* contains the equivalent of 10 µg of lead. ▲▲ (ERR 1-May-2019)

Sample solution: Dissolve 20.0 g of Inositol in diluted acetic acid, and dilute with diluted acetic acid to 100 mL. Add 2.0 mL of a saturated ammonium pyrrolidinedithiocarbamate solution (containing about 10 g of ammonium pyrrolidinedithiocarbamate per L) and 10.0 mL of methyl isobutyl ketone, and shake for 30 s. Protect from bright light. Allow the two layers to separate, and use the methyl isobutyl ketone layer.

Blank solution: Prepare as directed for the *Sample solution*, except omit the use of Inositol.

Standard solutions: Prepare as directed for the *Sample solution*, except prepare three *Standard solutions* by adding 0.5, 1.0, and 1.5 mL, respectively, of the *Standard lead solution* in addition to the 20.0 g of Inositol to be examined.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption

Analytical wavelength: 283.3 nm

Lamp: Lead hollow-cathode

Flame: Air–acetylene

Analysis: Set the atomic absorption spectrometer to zero, using the *Blank solution*. Introduce the *Sample solution* and each of the three *Standard solutions* into the instrument, and record the steady absorbance reading. Plot the absorbance readings against the known concentrations of added lead (in µg), and draw a straight line. Extrapolate the line until it meets the concentration axis to obtain the concentration, in mg/kg, of lead in the sample.

Acceptance criteria: NMT 0.5 mg/kg

• ORGANIC IMPURITIES

Mobile phase, System suitability solution, and Sample solution: Proceed as directed in the Assay.

Standard solution: Transfer 2.0 mL of the *Standard solution*, prepared as directed in the Assay, to a 100-mL volumetric flask, and dilute with water to volume.

[NOTE—This solution contains 1 mg/mL of inositol.]

Chromatographic system: Proceed as directed in the Assay, except use an injection volume of 20 µL.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Inositol taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of any impurity from the *Sample solution*

r_S = peak response of inositol from the *Standard solution*