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Hydrogenated Polydextrose

DEFINITION

Hydrogenated Polydextrose is obtained by transition metal catalytic hydrogenation of Polydextrose in aqueous solution. It contains NLT 90.0% of dextrose polymer units, calculated on the anhydrous and ash-free basis. The polymer chain end groups are mainly sorbitol-terminated.

IDENTIFICATION

• A.

Sample: 1 drop of a solution (1 in 10)

Analysis: Add 4 drops of 5% phenol solution to the *Sample* and then rapidly add 15 drops of sulfuric acid TS.

Acceptance criteria: A deep yellow to orange color is produced.

• B.

Sample: 1 mL of a solution (1 in 10)

Analysis: With vigorous swirling, add 1 mL of acetone to the *Sample*.

Acceptance criteria: The solution remains clear.

• C.

Sample: Solution obtained in *Identification B*

Analysis: With vigorous swirling, add 2 mL of acetone to the *Sample*.

Acceptance criteria: A heavy, milky turbidity develops immediately.

• D.

Sample: 1 mL of a solution (1 in 50)

Analysis: Add 4 mL of alkaline cupric citrate TS to the *Sample*. Boil vigorously for 2–4 min. Remove from heat, and allow the precipitate (if any) to settle.

Acceptance criteria: The supernatant is blue or blue-green.

• E. Meets the requirements for dextrose in *Organic Impurities, Procedure 2, Limit of Monomers*

Add the following:

▲ • F. Chromatographic Identity

Analysis: Proceed as directed in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (NF 1-May-2023)

ASSAY

Change to read:

• PROCEDURE

Mobile phase: 0.001 N sulfuric acid, ▲ prepared as follows. Cautiously transfer 3 mL of sulfuric acid into a 100-mL volumetric flask containing approximately 80 mL of water, dissolve, and dilute with water to volume. Pipet 1 mL of the resulting solution into a 1000-mL volumetric flask, and dilute with water to volume. Proportionally larger volumes of the second dilution may be prepared if desired. ▲ (NF 1-May-2023)

Standard solution: 4.0 mg/mL of ▲ [USP Hydrogenated Polydextrose RS](#) ▲ (NF 1-May-2023) in *Mobile phase*

Sample solution: 4.0 mg/mL of Hydrogenated Polydextrose in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Refractive index

Detector temperature: 35 ± 0.1°

Columns**Guard:** 4.6-mm × 3.0-cm; packing [L17](#)**Analytical:** 7.8-mm × 30-cm; packing [L17](#)**Flow rate:** 0.6 mL/min**Injection volume:** 20 µL**System suitability****Sample:** *Standard solution***Suitability requirements****Relative standard deviation:** NMT 2.0%**Analysis**

Samples: *Standard solution* and *Sample solution*. ▲[NOTE—Integrate and include smaller peaks eluted on the tailing of the Hydrogenated Polydextrose to be included as a part of the Assay.]▲ (NF 1-May-2023)

Calculate the percentage of dextrose polymer units in the portion of Hydrogenated Polydextrose taken:

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

r_U = peak response of dextrose polymer units from the *Sample solution*

r_S = peak response of dextrose polymer units from the *Standard solution*

C_S = concentration of ▲[USP Hydrogenated Polydextrose RS](#)▲ (NF 1-May-2023) in the *Standard solution* (mg/mL)

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

Acceptance criteria: NLT 90.0% on the anhydrous and ash-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%

• **LIMIT OF LEAD**

[NOTE—Use reagent-grade chemicals with a lead content of as low as possible, as well as high-purity water and gases. Before use in this analysis, rinse all glassware and plasticware twice with 10% nitric acid and twice with 10% hydrochloric acid, and then rinse them thoroughly with Purified Water.]

Matrix modifier solution: 10.0 mg/mL of dibasic ammonium phosphate

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 milliliter of the *Standard lead solution* contains the equivalent of 10 µg of lead.

Standard solution A: 0.02 µg/mL of lead, from the *Standard lead solution* in water

Standard solution B: 0.05 µg/mL of lead, from the *Standard lead solution* in water

Standard solution C: 0.1 µg/mL of lead, from the *Standard lead solution* in water

Standard solution D: 0.2 µg/mL of lead, from the *Standard lead solution* in water

Standard solution E: 0.5 µg/mL of lead, from the *Standard lead solution* in water

Sample solution: Transfer 1.0 g of Hydrogenated Polydextrose, weighed and calculated on the anhydrous and ash-free basis, into a 10-mL volumetric flask, dissolve in and dilute with water to volume.

Spiked sample solution: Transfer 1.0 g of Hydrogenated Polydextrose, weighed and calculated on the anhydrous and ash-free basis, into a 10-mL volumetric flask, and dissolve in water. Add 100 µL of the *Standard lead solution*, and dilute with water to volume. This solution contains 0.1 µg/mL of added lead.

Instrumental conditions

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

Mode: Graphite furnace atomic absorption spectrophotometer, equipped with a pyrolytic tube with a platform

Lamp: A lead hollow-cathode lamp, using a slit width of 0.7 mm (set low) and a deuterium arc lamp for background correction

Analytical wavelength: Lead emission line of 283.3 nm

Autosampler

Sample volume: 10 µL

Alternative volume: 10 µL of *Matrix modifier solution*

Furnace program: See the temperature program in [Table 1](#).

Table 1

Step	Dry	Char	Atomize	Clean	Recharge
Temperature (°)	130	800	2400	2600	20
Ramp time (s)	20	20	0	1	2
Hold time (s)	40	40	6	5	20
Argon flow rate (mL/min)	300	300	50	300	300

Analysis

Samples: 10 µL of the *Matrix modifier solution* was added into each of the 10-µL aliquots of the 5 *Standard solutions* (*Standard solutions A–E*), a mixture of 10 µL of the *Matrix modifier solution* and 10 µL of the *Sample solution*, and a mixture of 10 µL of the *Matrix modifier solution* and 10 µL of the *Spiked sample solution*.

Concomitantly determine the absorbances of the *Samples* using the *Instrumental conditions* described. Plot the absorbance of each *Standard solution*, compensated for background correction, versus its content of lead, in µg/mL, and draw the best straight line fitting the five points. From this plot, determine the concentrations, C_T and C_{ST} , in µg/mL, of lead in the *Sample solution* and the *Spiked sample solution*, respectively.

Calculate the percentage recovery taken:

$$\text{Result} = [(C_{ST} - C_T)/A] \times 100$$

A = quantity of lead added to the *Spiked sample solution*, 0.1 µg/mL

Calculate the content, in µg/g, of lead in the portion of Hydrogenated Polydextrose taken:

$$\text{Result} = (C_T/W) \times V$$

W = weight of Hydrogenated Polydextrose taken to prepare the *Sample solution* (g)

V = volume of the *Sample solution*, 10 mL

Acceptance criteria: NMT 0.5 µg/g; recovery is 80%–120%

Change to read:

• LIMIT OF NICKEL

▲Digest solution: Add 50 mL of [nitric acid, ultratrace](#) to a 1000-mL volumetric flask containing 500 mL of water. Mix and dilute with water to volume.

Nickel standard stock solution: 10 µg/mL of ICP Nickel (or multi-element) standard in 5% nitric acid solution. [NOTE—Single-element and multi-element ICP standard solutions are commercially available.¹]

Standard solution A: Pipet 1 mL from the *Nickel standard stock solution* to a 100-mL volumetric flask. Dilute with *Digest solution* to volume and mix. This solution contains 0.1 µg/mL of nickel.

Standard solution B: Pipet 2 mL from the *Nickel standard stock solution* to a 100-mL volumetric flask. Dilute with *Digest solution* to volume and mix. This solution contains 0.2 µg/mL of nickel.

Standard solution C: Pipet 5 mL from the *Nickel standard stock solution* to a 100-mL volumetric flask. Dilute with *Digest solution* to volume and mix. This solution contains 0.5 µg/mL of nickel.

Sample solution: Transfer 5 g of Hydrogenated Polydextrose into a 100-mL volumetric flask, and dissolve in and dilute with *Digest solution* to volume.

Blank solution: Use a fresh aliquot of the *Digest solution*.

Chromatographic system

(See [Plasma Spectrochemistry \(730\)](#).)