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Dextran 40 in Dextrose Injection

DEFINITION

Dextran 40 in Dextrose Injection is a sterile solution of Dextran 40 and Dextrose in Water for Injection. It contains in each 100 mL NLT 9.0 g and NMT 11.0 g of Dextran 40 and NLT 4.5 g and NMT 5.5 g of dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$). It contains no bacteriostatic agents.

IDENTIFICATION

• **A.**

Diluent: Dextrose (4.5 in 100)

Sample solution: Injection, diluted with *Diluent* to 10 mg/mL of dextran 40

Analysis: Using a capillary tube viscometer having dimensions such that the flow time of water is NLT 100 s, measure the flow times of the *Diluent* and of the *Sample solution* at 20°.

Calculate the intrinsic viscosity:

$$\text{Result} = \{\ln[R_D \times (t/t_0)]\}/C$$

R_D = ratio of the density of the *Sample solution* to that of the *Diluent*

t = flow time of the *Sample solution*

t_0 = flow time of the *Diluent*

C = concentration of dextran 40 in the *Sample solution* (g/mL)

Acceptance criteria: 18–23 mL/g

ASSAY

• **Dextrose**

Mobile phase: 0.01 N sulfuric acid, filtered and degassed

System suitability solution: 5 mg/mL each of dextrose and xylitol in water

Standard solution: USP Dextrose RS, diluted to 5 mg/mL of dextrose monohydrate in water

Sample solution: Transfer an accurately measured volume of Injection, equivalent to about 250 mg of dextrose monohydrate, to a 50-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm; packing L17

Temperatures: Column and, if necessary, detector are maintained at a constant temperature of about 40°.

Flow rate: 0.6 mL/min

Injection volume: 50 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.5 between the dextrose and xylitol peaks, *System suitability solution*

Relative standard deviation: NMT 1.5% for dextrose, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration of dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$), in g/100 mL, in the volume of Injection taken:

$$\text{Result} = (r_U/r_S) \times C \times D \times (M_{r1}/M_{r2})$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C = concentration of USP Dextrose RS in the *Standard solution* (g/100 mL)

D = dilution factor for the *Sample solution*

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of dextrose, 180.16

Acceptance criteria: 4.5–5.5 g/100 mL of dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$)

- **Dextran 40**

Sample solution: To 25 mL of Injection add 1 drop of 5 N ammonium hydroxide.

Analysis: Determine the optical rotation (see *Optical Rotation ⟨781⟩*).

Calculate the concentration, in g/100 mL, of dextran 40 in the volume of Injection taken:

$$\text{Result} = (1/Av_1) \times \{[(F \times a)/l] - [Av_2 \times C_d \times (M_{r2}/M_{r1})]\}$$

Av_1 = average value for the specific rotation of dextran 40, 197.5

F = conversion factor for 100 mL, 100

a = observed optical rotation (°)

l = length of the polarimeter tube (dm)

Av_2 = average value for the specific rotation of dextrose, 52.75

C_d = concentration of dextrose monohydrate as determined in the *Assay* for *Dextrose* (g/100 mL)

M_{r2} = molecular weight of dextrose, 180.16

M_{r1} = molecular weight of dextrose monohydrate, 198.17

Acceptance criteria: 9.0–11.0 g/100 mL

IMPURITIES

- **Limit of 5-Hydroxymethylfurfural and Related Substances**

Sample solution: Dilute Injection with water to 2.0 mg/mL of dextrose monohydrate ($C_6H_{12}O_6 \cdot H_2O$).

Instrumental conditions

Analytical wavelength: 284 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Sample solution* and *Blank*

Acceptance criteria: Absorbance NMT 0.25

SPECIFIC TESTS

- **pH ⟨791⟩:** 3.0–7.0
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 1.0 USP Endotoxin Unit/mL
- **Sterility Tests ⟨71⟩:** Meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*
- **Color of Solution:** Absorbance, determined at 375 nm against a water blank, is NMT 0.06.
- **Other Requirements:** It meets the requirements in *Injections ⟨1⟩* and *Particulate Matter in Injections ⟨788⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose glass or plastic containers.
- **Labeling:** The label states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, the label alternatively may state the total osmolar concentration in mOsmol/mL.
- **USP Reference Standards ⟨11⟩**

USP Dextrose RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DEXTRAN 40 IN DEXTROSE INJECTION	Jennifer Tong Sun Senior Scientist II	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: Chromatographic Database

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