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Dextran 40 in Sodium Chloride Injection

DEFINITION

Dextran 40 in Sodium Chloride Injection is a sterile solution of Dextran 40 and Sodium Chloride in Water for Injection. It contains in each 100 mL NLT 9.0 g and NMT 11.0 g of Dextran 40; and NLT 0.81 g and NMT 0.99 g of sodium chloride. It contains no bacteriostatic agents.

IDENTIFICATION

• A.

Diluent: Sodium chloride solution (0.9 in 100)

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

Analysis: Using a capillary tube viscometer with a flow time for water of 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 = *Sample solution* flow time

t_0 = *Diluent* flow time

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

Acceptance criteria: 18–23 mL/g

ASSAY

• SODIUM CHLORIDE

Sample solution: Pipet a volume of Injection, equivalent to 90 mg of chloride, into a porcelain casserole, and add 100 mL of water and 1 mL of dichlorofluorescein TS.

Analysis: Titrate with 0.1 N silver nitrate VS until the silver chloride flocculates and the mixture acquires a faint pink color. Each mL of 0.1 N silver nitrate VS is equivalent to 5.844 mg of sodium chloride.

Acceptance criteria: 0.81–0.99 g of sodium chloride per 100 mL

• 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 per 100 mL, of Dextran 40 in the portion of Injection taken:

$$\text{Result} = (a/l) \times (1/A_v) \times 100$$

a = observed optical rotation (°)

l = length of the polarimeter tube (dm)

A_v = average value for the specific rotation of Dextran 40, 197.5

Acceptance criteria: 9.0–11.0 g of Dextran 40 per 100 mL

IMPURITIES

SPECIFIC TESTS

- [pH \(791\)](#): 3.5–7.0
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): It contains NMT 1.0 USP Endotoxin Unit/mL.

- **STERILITY TESTS (71):** It meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **COLOR OF SOLUTION:** Its absorbance, determined at 375 nm against a water blank, is NMT 0.05.
- **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.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DEXTRAN 40 IN SODIUM CHLORIDE INJECTION	Jennifer Tong Sun Senior Scientist II	BI032020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: [Chromatographic Database](#)

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