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Fructose Injection

DEFINITION

Fructose Injection is a sterile solution of Fructose in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of fructose ($C_6H_{12}O_6$). Fructose Injection contains no antimicrobial agents.

IDENTIFICATION

• **A.**

Silver nitrate solution: Dissolve 0.6 g of silver nitrate in 2.0 mL of water in a 100-mL volumetric flask, dilute with acetone to volume.

Sodium hydroxide solution: Dissolve 2.0 g of sodium hydroxide in 5.0 mL of water in a 100-mL volumetric flask, dilute with alcohol to volume.

Alcoholic monobasic sodium phosphate: Dissolve 4.0 g of monobasic sodium phosphate in 150 mL of water. Add, with mixing, 500 mL of alcohol. Use the entire mixture, even if there are two phases. Prepare the solution fresh daily.

Standard solution: 2.5 mg/mL of USP Fructose RS

Sample solution: Nominally 2.5 mg/mL of fructose from a volume of Injection diluted with water

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: Acetone, *n*-butyl alcohol, and water (50:40:10)

Analysis

Samples: *Standard solution* and *Sample solution*

Immerse the TLC plate coated side down in *Alcoholic monobasic sodium phosphate* for 2.0 min. Remove the plate from the solution, place it coated side up on a clean, absorbent towel, dry it in a current of warm air, and activate it at 105° for 30 min. Cool to room temperature, and apply the *Standard solution* and the *Sample solution*. Allow the spots to dry, and develop the chromatogram in the *Developing solvent system*. Remove the plate, allow the solvent to evaporate, and spray the plate with *Silver nitrate solution*. Allow the plate to dry for 30 s, then spray with *Sodium hydroxide solution*.

Acceptance criteria: The R_F value of the spot appearing within 3 min from the *Sample solution* corresponds to that from the *Standard solution*.

ASSAY

• **Procedure**

Sample solution: Transfer an accurately measured volume of Injection, equivalent to 5 g of fructose, to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, dilute with water to volume, and mix.

Analysis: After 30 min, determine the angular rotation (see *Optical Rotation* ⟨781⟩), and record the observed rotation, α, as an absolute number.

Calculate the percentage of the labeled amount of fructose ($C_6H_{12}O_6$) in the portion of Injection taken:

$$\text{Result} = [(F \times \alpha)/(l \times V \times L)] \times 100$$

F = correction factor, 1124

l = length of the polarimeter tube (dm)

V = volume of Injection taken (mL)

L = labeled amount of fructose in Injection (mg/mL)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **Limit of Hydroxymethylfurfural**

Resorcinol solution: 10 mg/mL of resorcinol in hydrochloric acid

Sample solution: Nominally 100 mg/mL of fructose from a volume of Injection diluted with water

Analysis: To 10 mL of *Sample solution* add 5 mL of ether, and shake vigorously. Transfer 2 mL of the ether layer to a test tube, and add 1 mL of *Resorcinol solution*.

Acceptance criteria: A slight pink color may develop, but no cherry-red color appears immediately.

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.5 USP Endotoxin Units/mL
- **pH ⟨791⟩**

  Analysis: Dilute a portion with water, if necessary, to NMT 5% of fructose. Add 0.3 mL of a saturated potassium chloride solution for each 100 mL.

  Acceptance criteria: 3.0–6.0
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I or Type II glass.
- **Labeling:** The label states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection, but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol/mL.
- **USP Reference Standards ⟨11⟩**

  USP Fructose RS

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

Topic/Question	Contact	Expert Committee
FRUCTOSE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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