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Fructose and Sodium Chloride Injection

» Fructose and Sodium Chloride Injection is a sterile solution of Fructose and Sodium Chloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amounts of $C_6H_{12}O_6$ (fructose) and of NaCl (sodium chloride). Fructose and Sodium Chloride Injection contains no antimicrobial agents.

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 per 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 per mL.

USP Reference standards ⟨11⟩—
USP Fructose RS

Identification—It responds to the *Identification* tests under *Fructose Injection* and to the tests for *Sodium* ⟨191⟩ and for *Chloride* ⟨191⟩.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 0.5 USP Endotoxin Unit per mL.

pH ⟨791⟩: between 3.0 and 6.0.

Limit of hydroxymethylfurfural—It meets the requirements of the test for Hydroxymethylfurfural under *Fructose*.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay for fructose—Transfer an accurately measured volume of Injection, containing about 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. After 30 minutes determine the angular rotation (see *Optical Rotation* ⟨781⟩), and record the observed rotation, *a*, as an absolute number. Calculate the quantity, in mg, of fructose ($C_6H_{12}O_6$) in each mL of the Injection taken by the formula:

$$1124a/lV$$

in which *l* is the length, in dm, of the polarimeter tube; and *V* is the volume, in mL, of Injection taken.

Assay for sodium chloride—Transfer an accurately measured volume of Injection, equivalent to about 90 mg of sodium chloride, to a conical flask, evaporate to a volume of about 10 mL, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride (NaCl).

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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