Invert Sugar Injection

Invert Sugar Injection is a sterile solution of a mixture of equal amounts of Dextrose and Fructose in Water for Injection, or an equivalent sterile solution produced by the hydrolysis of Sucrose, in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of C₆H₁₂O₆. It contains no antimicrobial agents.

NOTE—Invert Sugar Injection that is produced by mixing Dextrose and Fructose is exempt from the requirement of the test for Completeness of inversion.

Packaging and storage—Preserve in single-dose containers, preferably of Type I or Type II glass, or of a suitable plastic material.

Labeling—The label states the total osmolar concentration in mOsmol per L.

USP Reference standards (11)—
USP Endotoxin RS

Identification—Add a few drops of Injection to 5 mL of hot alkaline cupric tartrate TS: a copious red precipitate of cupric oxide is formed.

Bacterial endotoxins (85)—It contains not more than 0.5 USP Endotoxin Unit per mL.

pH (791): between 3.0 and 6.5.

Chloride (221)—A 2.0-mL portion shows no more chloride than corresponds to 0.34 mL of 0.020 N hydrochloric acid (0.012%).

Heavy metals (231)—Transfer a volume of Injection, equivalent to 4.0 g of invert sugar, to a suitable vessel, and adjust the volume to 25 mL by evaporation: the limit is 0.0005 percent of invert sugar per mL of Injection.

Limit of 5-hydroxymethylfurfural and related substances—Dilute an accurately measured volume of Injection, equivalent to 1.0 g of invert sugar, with water to 500.0 mL. Determine the absorbance of this solution in a 1-cm cell at 284 nm, with a suitable spectrophotometer, using water as the blank: the absorbance is not more than 0.25.

Completeness of inversion—

Mobile phase—Use filtered, degassed water.

Standard preparation—Prepare a solution in water containing known concentrations of about 0.25 mg of sucrose and about 12.5 mg of dextrose per mL.

Test preparation—Transfer a volume of Injection, equivalent to about 2.5 g of invert sugar, to a 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a refractive index detector and a 7.8-mm x 30-cm column that contains 9-µm packing L19, maintained at a constant temperature of about 40°C. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the sucrose elutes first, and the peak is baseline separated from the dextrose peak. The relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the Standard preparation and the Test preparation into the chromatograph, record the chromatograms, and measure the responses for the sucrose peaks. Calculate the quantity, in mg, of sucrose, in the volume of the Injection taken by the formula:

\[
100C \left( \frac{r_U}{r_S} \right)
\]

in which C is the concentration, in mg per mL, of sucrose in the Standard preparation, and \(r_U\) and \(r_S\) are the peak responses obtained from the Standard preparation and the Test preparation, respectively.

Sulbactam Sodium

Sulbactam Sodium contains not less than 886 µg and not more than 941 µg of sulbactam (C₁₇H₁₇NO₃) per mg, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.
**USP Reference standards** (11)—
USP Endotoxin RS
USP Sulbactam RS

**Identification**—
A: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.
B: It meets the requirements of the tests for Sodium (191).

**Crystallinity** (695): meets the requirements.

**Bacterial endotoxins** (85)—Where the label states that Sulbactam Sodium is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains not more than 0.17 USP Endotoxin Unit per mg of sulbactam.

**Sterility** (71)—Where the label states that Sulbactam Sodium is sterile, it meets the requirements when tested as directed for Membrane Filtration under Test for Sterility of the Product to be Examined.

**Water, Method I** (921): not more than 1.0%.

**Assay**—
0.005 M Tetrabutylammonium hydroxide—Dilute 6.6 mL of a 40% solution of tetrabutylammonium hydroxide with water to obtain 1800 mL of solution. Adjust with 1 M phosphoric acid to a pH of 5.0 ± 0.1, dilute with water to 2000 mL, and mix.  

Mobile phase—Prepare a filtered and degassed mixture of 0.005 M Tetrabutylammonium hydroxide and acetonitrile (1650:350). Make adjustments if necessary (see System Suitability under Chromatography (621)).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Sulbactam RS in Mobile phase to obtain a solution having a known concentration of about 1 mg per mL. [NOTE—Invert this solution promptly.]

Assay preparation—Transfer about 110 mg of Sulbactam Sodium, accurately weighed, to a 100-mL volumetric flask, and dilute with Mobile phase to volume, and mix. [NOTE—Invert this solution promptly.]

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 230-nm detector and a 4-mm x 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the column efficiency determined from the analyte peak is not less than 3500 theoretical plates; the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in µg, of sulbactam (C8H11NO5S) in each mg of Sulbactam Sodium taken by the formula:

\[
1000(CP / W)(r_0 / r_s)
\]

in which C is the concentration, in mg per mL, of USP Sulbactam RS in the Standard preparation; P is the assigned sulbactam content, in µg per mg, of USP Sulbactam RS; W is the quantity, in mg, of Sulbactam Sodium taken to prepare the Assay preparation; and r_0 and r_s are the peak areas for sulbactam obtained from the Assay preparation and the Standard preparation, respectively.

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**Sulconazole Nitrate**

C_{18}H_{15}Cl_{3}N_{2}S · HNO_{3} 460.76

1H-Imidazole, 1-[2-[(4-chlorophenyl)methyl]thio]-2-(2,4-dichlorophenyl)ethy]-mononitrate, (±).  

(±)-1-[2,4-Dichloro-β-[p-chlorobenzyl]thio]-phenethyl-imidazole mononitrate [61318-91-0].

» Sulconazole Nitrate contains not less than 98.0% and not more than 102.0% of C_{18}H_{15}Cl_{3}N_{2}S · HNO_{3}, calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed containers, protected from light.

**USP Reference standards** (11)—
USP Sulconazole Nitrate RS

**Identification**—
A: Infrared Absorption (197K).
B: A solution of it responds to the ferric sulfate-sulfuric acid test for Nitrate (191).

**Loss on drying** (731)—Dry it in vacuum at 80°C for 3 hours: it loses not more than 1.0% of its weight.

**Residue on ignition** (281): not more than 0.1%.

**Ordinary impurities** (466)—

Test solution—Prepare a solution of it, in a mixture of dichloromethane and methanol (2:1), having an accurately known concentration of 20 mg per mL.

Standard solutions—Dissolve USP Sulconazole Nitrate RS in a mixture of dichloromethane and methanol (2:1), and dilute quantitatively with the same mixture to obtain separate solutions having accurately known concentrations of 0.02, 0.1, 0.2, and 0.4 mg per mL, respectively.

Eluant: a mixture of methylene chloride, cyclohexane, and diethylamine (50:45:5).

Visualization: 22.

**Assay**—

Mobile phase—Dissolve 1.9 g of sodium 1-pentanesulfonate in 300 mL of water, add 700 mL of methanol, and mix. Adjust with 2 N sulfuric acid to an apparent pH of 3.8 ± 0.1, filter, and degas. Make adjustments if necessary (see System Suitability under Chromatography (621)).

Standard preparation—Dissolve an accurately weighed quantity of USP Sulconazole Nitrate RS in Mobile phase, and dilute quantitatively, and stepwise if necessary, with Mobile phase to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer about 20 mg of Sulconazole Nitrate, accurately weighed, to a 100-mL volumetric flask, and dilute with Mobile phase to volume, and mix.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm x 25-cm column that contains packing L1 and is maintained at 40 ± 1.0°C. The flow rate is about 2 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the column efficiency determined from the analyte peak is not less than 1500 theoretical plates, the tailing factor for the sulconazole nitrate peak is not more than 2.3, and the relative standard deviation for replicate injections is not more than 1.5%.