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Diatrizoate Sodium Injection

» Diatrizoate Sodium Injection is a sterile solution of Diatrizoate Sodium in Water for Injection, or a sterile solution of Diatrizoic Acid in Water for Injection prepared with the aid of Sodium Hydroxide. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of diatrizoate sodium ($C_{11}H_8I_3N_2NaO_4$). It may contain small amounts of suitable buffers and of Edetate Calcium Disodium or Edetate Disodium as a stabilizer. Diatrizoate Sodium Injection intended for intravascular use contains no antimicrobial agents.

Packaging and storage—Preserve Injection intended for intravascular injection in single-dose containers, preferably of Type I or Type III glass, protected from light. Injection intended for other than intravascular use may be packaged in 100-mL multiple-dose containers, preferably of Type I or Type III glass, protected from light.

Labeling—Label containers of Injection intended for intravascular injection to direct the user to discard any unused portion remaining in the container. Label containers of Injection intended for other than intravascular injection to show that the contents are not intended for intravascular injection.

USP Reference standards ⟨11⟩—

USP Diatrizoic Acid RS
USP Diatrizoic Acid Related Compound A RS

5-Acetamido-3-amino-2,4,6-triiodobenzoic acid.

$C_9H_7I_3N_2O_3$ 571.88

Identification—

A: Dilute a volume of Injection, if necessary, with a 0.8 in 1000 solution of sodium hydroxide in methanol to obtain a test solution having a concentration of 1 mg per mL. The test solution responds to the *Thin-layer Chromatographic Identification Test* ⟨201⟩, the Standard solution being prepared at a concentration of 1 mg of USP Diatrizoic Acid RS per mL in a 0.8 in 1000 solution of sodium hydroxide in methanol, the solvent mixture being a mixture of chloroform, methanol, and ammonium hydroxide (20:10:2), and short-wavelength UV light being used to locate the spots.

B: Evaporate a volume of Injection, equivalent to about 500 mg of diatrizoate sodium, to dryness, and heat the residue so obtained in a crucible: violet vapors are evolved.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 5.6 USP Endotoxin Units per mL for Injections containing 20% of diatrizoate sodium; not more than 1.3 USP Endotoxin Units per mL for Injections containing 25% of diatrizoate sodium; and not more than 5.0 USP Endotoxin Units per mL for Injections containing 50% of diatrizoate sodium.

pH ⟨791⟩: between 6.0 and 7.7.

Iodine and iodide—Using a volume of Injection equivalent to 2.0 g of diatrizoate sodium, and diluting it with water to 24 mL in a 50-mL centrifuge tube provided with a stopper, proceed as directed for *Procedure* in the test for *Iodine and iodide* under *Diatrizoate Meglumine*.

Free aromatic amine—Transfer a volume of Injection, equivalent to 1.0 g of diatrizoate sodium, to a 50-mL volumetric flask, dilute with water to 5 mL, and add 10 mL of 0.1 N sodium hydroxide. Proceed as directed in the test for *Free aromatic amine* under *Diatrizoate Meglumine*, beginning with "To a second 50-mL volumetric flask transfer 4 mL of water."

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

Assay—Pipet into a glass-stoppered 125-mL conical flask a volume of Injection, equivalent to about 500 mg of diatrizoate sodium. Add 30 mL of 1.25 N sodium hydroxide and 500 mg of powdered zinc, and reflux the mixture for 1 hour. Cool to room temperature, wash the condenser with 20 mL of water, and filter the mixture. Wash the flask and the filter with small portions of water, adding the washings to the filtrate. Add to the filtrate 5 mL of glacial acetic acid and 1 mL of tetrabromophenolphthalein ethyl ester TS, and titrate with 0.05 N silver nitrate VS until the color of the yellow precipitate just changes to green. Each mL of 0.05 N silver nitrate is equivalent to 10.60 mg of $C_{11}H_8I_3N_2NaO_4$.

Topic/Question	Contact	Expert Committee
DIATRIZOATE SODIUM INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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