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Ioxaglate Meglumine and Ioxaglate Sodium Injection

» Ioxaglate Meglumine and Ioxaglate Sodium Injection is a sterile solution of Ioxaglic Acid in Water for Injection, prepared with the aid of Meglumine and Sodium Hydroxide. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amounts of ioxaglate meglumine ($C_{24}H_{21}I_6N_5O_8 \cdot C_7H_{17}NO_5$) and iodine (I). It may contain small amounts of Edetate Calcium Disodium as a stabilizer.

Ioxaglate Meglumine and Ioxaglate Sodium Injection intended for intravascular use contains no antimicrobial agents.

Packaging and storage—Preserve in single-dose containers, preferably of Type I 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 indicate that the contents are not intended for intravascular injection.

USP Reference standards ⟨11⟩—

USP Ioxaglic Acid RS

Identification—

A: It responds to *Identification* test *A* under *Ioxaglic Acid*, a solution of 1.7 mL of Injection in 100 mL of water being used as the test solution.

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

pH ⟨791⟩: between 6.0 and 7.6.

Free iodine and iodide—

Test solution—Transfer a volume of Injection, equivalent to 2 g of the total of ioxaglate meglumine and ioxaglate sodium, to a 50-mL centrifuge tube, add 25 mL of water and 15 mL of 2 N sulfuric acid, and mix thoroughly. Centrifuge for 15 minutes, and decant the supernatant layer into a glass-stoppered 50-mL graduated cylinder. Repeat the sulfuric acid washing and centrifugation once more, adding the supernatant layer into the 50-mL graduated cylinder.

Procedure—Proceed as directed for *Procedure* in the test for *Free iodine and iodide* under *Ioxaglic Acid* (0.02% of iodide).

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

Assay for ioxaglate meglumine—Determine the angular rotation (see *Optical Rotation ⟨781⟩*) of the Injection, using a 10-cm cell and a suitable polarimeter. Calculate the percentage of ioxaglate meglumine in the Injection taken by the formula:

$$100a/3.32$$

in which a is the observed angular rotation, in degrees, corrected for a water blank; and 3.32 is the specific rotation, in degrees, of ioxaglate meglumine.

Assay for iodine—Transfer an accurately measured volume of Injection, equivalent to about 5 g (total) of ioxaglate meglumine and ioxaglate sodium, to a 250-mL volumetric flask, dilute with water to volume, and mix. Pipet 25 mL of this solution into a 125-mL conical flask, add 12 mL of 5 N sodium hydroxide and 1 g of powdered zinc, connect the flask to a reflux condenser, and reflux for 30 minutes. Proceed as directed in the *Assay for iodine* under *Ioxaglic Acid*. Each mL of 0.05 N silver nitrate is equivalent to 6.345 mg of iodine (I).

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

Topic/Question	Contact	Expert Committee
IOXAGLATE MEGLUMINE AND IOXAGLATE SODIUM INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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