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Iopromide Injection

» Iopromide Injection is a sterile solution of Iopromide in Water for Injection. It contains not less than 94.0 percent and not more than 105.0 percent of the labeled amount of iopromide ($C_{18}H_{24}I_3N_3O_8$). It may contain small amounts of suitable buffers and of Edetate Calcium Disodium as a stabilizer. It contains no antimicrobial agents.

Packaging and storage—Preserve in single-dose glass containers as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging*, and protect from light. Store at controlled room temperature.

Labeling—Label Injection to state that it is not to be used if it contains particulate matter and that after use any unused portion remaining in the container is to be discarded. It is labeled also to state that it is not for intrathecal use.

USP Reference standards ⟨11⟩—

USP Iopromide RS
USP Iopromide Related Compound A RS
USP Iopromide Related Compound B RS

5-(Acetylamino)-*N*,*N*′-bis(2,3-dihydroxypropyl)-2,4,6-triiodo-*N*-methyl-1,3-benzenedicarboxamide.

Identification—

A: Evaporate 3 mL of Injection to dryness, and heat the residue so obtained in a crucible in a hood: violet vapors are evolved.

B: The R_F value of the principal spot in the chromatogram obtained from the *Test solution*, developed with the *Basic eluant*, in the test for *Ordinary impurities* corresponds to that obtained from the *Standard solution* similarly tested.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.25 USP Endotoxin Units per mL of Injection.

pH ⟨791⟩**:** between 6.5 and 8.0.

Free iodine—Transfer a volume of Injection, equivalent to 2 g of iopromide, to a 50-mL centrifuge tube. Dilute with water to 24 mL. Add 2 mL of toluene and 2 mL of diluted sulfuric acid solution, and shake: the toluene layer shows no red color.

Limit of free iodide—Transfer 10.0 mL of Injection and 50 mL of water to a 150-mL titration vessel, and titrate with 0.001 N silver nitrate VS using a silver or platinum electrode in combination with a reference electrode, determining the endpoint potentiometrically. Each mL of 0.001 N silver nitrate is equivalent to 126.9 µg of I. The limit is 80 µg of iodide per g of iopromide, based on the labeled content of iopromide.

Limit of free aromatic amine—Proceed as directed in the test for *Limit of free aromatic amine* under *Iopromide*, except to prepare the *Test solution* as follows. Transfer an accurately measured volume of Injection, equivalent to about 500 mg of iopromide, to a 25-mL volumetric flask, dilute with water to 20 mL, and mix. Calculate the percentage of free aromatic amine based on the labeled amount of iopromide in the Injection taken by the formula:

$$10(W_S/CV)(A_U/A_S)$$

in which W_S is the quantity, in mg, of USP Iopromide Related Compound A RS taken to prepare the *Standard solution*; C is the labeled concentration, in mg per mL, of iopromide in the Injection used to prepare the *Test solution*; V is the volume, in mL, of Injection to prepare the *Test solution;* and A_U and A_S are the absorbances of the *Test solution* and the *Standard solution*, respectively: not more than 0.2% is found.

Limit of *N*-acetyl compound (iopromide related compound B)—Using the chromatogram of the *Assay preparation* obtained in the *Assay*, calculate the percentage of *N*-acetyl compound in the iopromide in the Injection taken by the formula:

$$(W_B/C)[(A_{Y1} + A_{Y2})/(R_{Y1} + R_{Y2})]$$

in which W_B is the quantity, in mg, of USP Iopromide Related Compound B RS taken to prepare the *Related compound B standard solution*; C is the concentration, in mg of iopromide per mL, in the *Assay preparation* based on the labeled amount and the extent of dilution; A_{Y1} and A_{Y2} are the peak responses for iopromide related compound B *Y*1- and *Y*2-isomers, respectively, from the *Assay preparation*; and R_{Y1} and R_{Y2} are the peak responses for iopromide related compound B *Y*1- and *Y*2-isomers, respectively, from the *Related compound B standard solution:* not more than 1.5% is found.

Isomer distribution—Using the chromatogram of the *Assay preparation* obtained in the *Assay*, calculate the percentage of iopromide isomers in the iopromide in the Injection taken by the formula:

$$100(r_i)/(r_{E1} + r_{E2} + r_{Z1} + r_{Z2})$$

in which r_i is the peak response of each individual iopromide isomer; and r_{E1}, r_{E2}, r_{Z1}, and r_{Z2}, are the peak responses for the iopromide *E*1-, *E*2-, *Z*1-, and *Z*2-isomers, respectively, from the *Assay preparation:* between 8.0% and 12.0% of the *E*1-isomer, between 9.0% and 14.0% of the *E*2-isomer, between 32.0% and 40.0% of the *Z*1-isomer, and between 38.0% and 46.0% of the *Z*2-isomer are found.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*, and meets the requirements for *Ordinary impurities* under *Iopromide*.

Assay—

Diluent, Mobile phase, Standard preparation, Related compound B standard solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Iopromide*.

Assay preparation—Dilute an accurately measured volume of Injection, quantitatively and stepwise, with *Diluent* to obtain a solution having a final nominal concentration of 1.9 mg of iopromide per mL.

Procedure—Proceed as directed in the *Assay* under *Iopromide*. Calculate the quantity, in mg, of iopromide ($C_{18}H_{24}I_3N_3O_8$) in each mL of the Injection taken by the formula:

$$(CL/D)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Iopromide RS in the *Standard preparation*; L is the labeled quantity, in mg, of iopromide in each mL of Injection; D is the concentration, in mg per mL, of iopromide in the *Assay preparation*, based on the volume of Injection taken and the extent of dilution; and the other factors are as defined therein.

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

Topic/Question	Contact	Expert Committee
IOPROMIDE 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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