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Ethiodized Oil Injection

» Ethiodized Oil Injection is an iodine addition product of the ethyl ester of the fatty acids of poppyseed oil, containing not less than 35.2 percent and not more than 38.9 percent of organically combined iodine. It is sterile.

Packaging and storage—Preserve in well-filled, light-resistant, single-dose or multiple-dose containers.

Identification—Place 1 drop in a test tube, and heat directly in a flame: the violet color of iodine vapors is observed.

Specific gravity ⟨841⟩: between 1.280 and 1.293, at 15°.

Viscosity—Capillary Methods ⟨911⟩ or **Viscosity—Rotational Methods ⟨912⟩:** between 50 centipoises and 100 centipoises, at 15°.

Sterility Tests ⟨71⟩: meets the requirements.

Acidity—Dissolve 1.0 mL in 10 mL of chloroform in a glass-stoppered cylinder, add phenolphthalein TS and 0.30 mL of sodium hydroxide solution (1 in 250), insert the stopper, and shake vigorously: a red color is produced.

Free iodine—Dissolve 1.0 mL in 5 mL of chloroform, add 20 mL of potassium iodide solution (1 in 20), agitate vigorously, and add 2 drops of starch TS: no blue color is produced.

Assay— [**Caution—**Observe rigorously the precautions set forth for Procedure under *Oxygen Flask Combustion ⟨471⟩*.]

Weigh accurately about 30 mg (1 drop) of Injection in a tared cellulose acetate capsule, and proceed as directed for *Procedure* under *Oxygen Flask Combustion ⟨471⟩*, beginning with "Place the specimen," and using a thick-walled, 500-mL combustion flask. Use 10 mL of sodium hydroxide solution (1 in 100) and 1 mL of freshly prepared sodium bisulfite solution (1 in 100) as the absorbing liquid. Pipet 1 mL of bromine-sodium acetate TS into the cup of the flask, loosen the stopper, and allow the solution to be sucked into the flask. Wash down the cup and the ground joint with water, insert the stopper in the flask, shake it vigorously, then add 5 drops of formic acid, and again shake the flask. Remove the stopper, and rinse the stopper and the specimen holder with water, collecting the rinsings in the flask. Bubble nitrogen through the solution to displace all of the oxygen from the solution and the flask. Add 0.50 g of potassium iodide and 3 mL of 2 N sulfuric acid, allow the mixture to stand for 2 minutes, add 3 mL of starch TS, and titrate the liberated iodine with 0.05 N sodium thiosulfate VS. Each mL of 0.05 N sodium thiosulfate is equivalent to 1.058 mg of iodine (I).

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

Topic/Question	Contact	Expert Committee
ETHIODIZED OIL INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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