Iopanoic acid (Acidum iopanoicum)

\[ C_{11}H_{12}I_3NO_2 \]

Relative molecular mass, 570.9

Chemical name. 3-Amino-α-ethyl-2,4,6-triiodohydrocinnamic acid; 3-amino-α-ethyl-2,4,6-triiodobenzenepropanoic acid; CAS Reg. No. 96-83-3.

Description. A light yellowish white powder; odour, faint, characteristic.

Solubility. Practically insoluble in water; soluble in ethanol (~750 g/l) TS, and acetone R; dissolves in solutions of alkali hydroxides.

Category. Radiocontrast medium.

Storage. Iopanoic acid should be kept in a tightly closed container, protected from light. Iopanoic acid is gradually affected by light.

Requirements

Iopanoic acid contains not less than 97.0% and not more than the equivalent of 101.0% of \( C_{11}H_{12}I_3NO_2 \), calculated with reference to the dried substance.

Identity tests

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from iopanoic acid RS or with the reference spectrum of iopanoic acid.

B. Heat strongly 0.05 g in a suitable crucible; violet vapours are evolved.

C. Melting temperature, about 155 °C with decomposition.

Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 3; determine the heavy metals content according to Method A; not more than 20 μg/g.

Iodides. Dissolve 0.8 g in a minimum quantity of sodium hydroxide (10 g/l) TS, dilute to 10 mL with water, add drop by drop nitric acid (~130 g/l) TS until complete precipitation is obtained, then add an excess of 3 mL. Filter, and wash the precipitate with 5 mL of water; to the filtrate add 1 mL of hydrogen peroxide (~330 g/l) TS and 1 mL of chloroform R, and shake. To serve as a reference solution, treat similarly 2 mL of iodide standard (20 μg I/mL) TS with 3 mL of nitric acid (~130 g/l) TS and sufficient water to equal the volume of the solution to be tested. Any red-violet colour in the chloroform layer is no darker than that obtained from the reference solution.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry at 105 °C for 1 hour; it loses not more than 10 mg/g.
**Assay.** Place about 0.4 g, accurately weighed, in a 125-mL conical flask and add 30 mL of sodium hydroxide (50 g/l) TS and 0.5 g of zinc R powder. Connect the flask to a reflux condenser and boil for 30 minutes. Cool the flask to room temperature, rinse the condenser with 20 mL of water into the flask, and filter the mixture. Rinse the flask and the filter thoroughly and add the rinsing to the filtrate. Add 5 mL of glacial acetic acid R and 1 mL of tetrabromophenolphthalein ethyl ester TS and titrate with silver nitrate (0.05 mol/l) VS until the yellow precipitate just changes to green.

Each mL of silver nitrate (0.05 mol/l) VS is equivalent to 9.516 mg of $C_{11}H_{12}I_3NO_2$. 