Iodine (Iodum) Molecular formula. I₂

Relative molecular mass. 253.8

Chemical name. lodine; CAS Reg. No. 7553-56-2.

Description. Heavy, greyish black plates or granules, having a metallic lustre.

Solubility. Very slightly soluble in water; soluble in ethanol (~750 g/l) TS; freely soluble in carbon tetrachloride R, carbon disulfide R, and ether R.

Category. External antiseptic.

Storage. lodine should be kept in a tightly closed container, preferably made of glass and provided with a glass stopper.

Additional information. lodine volatilizes slowly at room temperature giving violet, irritant vapours.

Requirements

Definition. lodine contains not less than 99.5% and not more than 100.5% of I.

Identity tests

A. Dissolve 0.05 g in 10 mL of ethanol (~750 g/l) TS; the colour of the solution is reddish brown. Dissolve 0.05 g in 10 mL of carbon tetrachloride R; the colour of the solution is violet.

B. To a saturated solution in water add starch TS; a blue colour is produced. Boil the mixture for a short time; the solution loses its colour, but on cooling the colour reappears.

Chlorides and bromides. Triturate 1.5 g with 10 mL of water, filter, wash the filter and dilute the filtrate to 15 mL with water. To the solution add 0.5 g of zinc R powder. When the solution has become decolourized, filter and wash the filter with sufficient water to adjust the volume of the filtrate to 20 mL. To 5 mL of the filtrate (keep the remaining filtrate for the test for cyanides) add 1.5 mL of ammonia (~260 g/l) TS and 3 mL of silver nitrate (40 g/l) TS, filter, wash the filter with sufficient water to adjust the volume of the filtrate to 10 mL, add 1.5 mL of nitric acid (~1000 g/l) TS and allow to stand for 1 minute. Any opalescence in the solution is not more intense than that obtained from a solution simultaneously prepared by mixing 10.75 mL of water, 0.25 mL of hydrochloric acid (0.01 mol/l) VS, 0.2 mL of nitric acid (~130 g/l) TS, and 0.3 mL of silver nitrate (40 g/l) TS; this indicates that the content of chlorides and bromides is not more than 0.25 mg/g.

Cyanides. To 5 mL of the filtrate obtained in the test for chlorides and bromides add 0.2 mL of ferrous sulfate (15 g/l) TS and 1 mL of sodium hydroxide (~80 g/l) TS. Heat for a few minutes and acidify with hydrochloric acid (~70 g/l) TS; no blue or green colour is produced.

Non-volatile residue. Place about 1 g, accurately weighed, in a porcelain dish and heat on a water-bath until the iodine has volatilized. Dry the residue for 1 hour at 105°C and weigh; not more than 1.0 mg/g.

Assay. Dissolve about 0.5 g of finely powdered test substance, accurately weighed, in a solution of 1 g of potassium iodide R in 5 mL of water. Dilute with water to about 50 mL, add 1 mL of hydrochloric acid (~70 g/l) TS and titrate with sodium thiosulfate (0.1 mol/l) VS, using starch TS as indicator. Each mL of sodium thiosulfate (0.1 mol/l) VS is equivalent to 12.69 mg of I.

Additional requirement for lodine for parenteral use

Complies with the monograph for "Parenteral preparations".