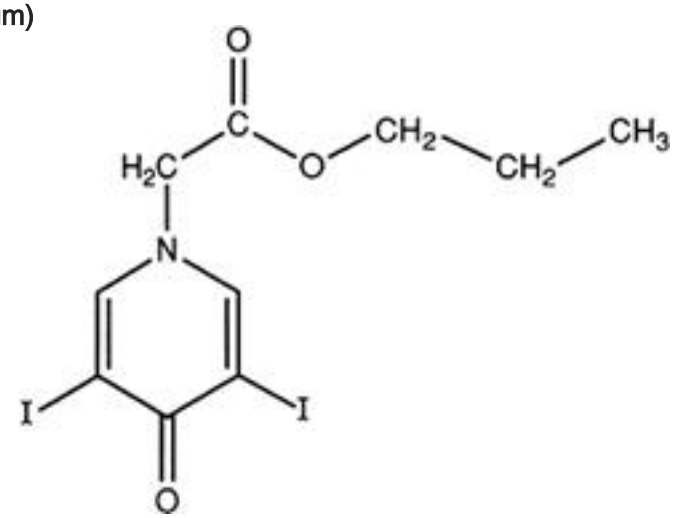
Propyliodone (Propyliodonum)



$C_{10}H_{11}I_2NO_3$

Relative molecular mass. 447.0

Chemical name. Propyl 3,5-diiodo-4-oxo-1(4*H*)-pyridineacetate; CAS Reg. No. 587-61-1.

Description. A white or almost white, crystalline powder; odourless or almost odourless.

Solubility. Practically insoluble in water; slightly soluble in ethanol (~750 g/l) TS; very slightly soluble in ether R.

Category. Radiocontrast medium.

Storage. Propyliodone should be kept in a tightly closed container, protected from light.

Requirements

Propyliodone contains not less than **99.0%** and not more than the equivalent of **101.0%** of $C_{10}H_{11}I_2NO_3$, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 20µg/mL solution in dehydrated ethanol R, when observed between 230nm and 350nm, exhibits 2 maxima at about 239nm and 281nm; the absorbances of a 1-cm layer at those wavelengths are about 0.64 and 0.52, respectively.

B. Heat 0.1 g with a few drops of sulfuric acid (~1760 g/l) TS in a suitable crucible; violet vapours are evolved.

Melting range. 187-190 °C.

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.

Halides. Shake 2.4 g with 30 mL of water for 15 minutes and filter. To 10 mL of the filtrate add 1 mL of nitric acid (~130 g/l) TS, 2 mL of sodium nitrite (1 g/l) TS, and 2 mL of chloroform R, shake well, and centrifuge. To serve as a reference solution, treat similarly 2 mL of iodide standard (20 µg I/mL) TS with 8 mL of water. The content of halides, expressed as iodides, does not produce a solution with any red-violet colour more intense than that of the reference solution.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry to constant mass at 105 °C; it loses not more than 5.0 mg/g.

Acidity. Dissolve 1 g in 40 mL of hot 1-propanol R, previously neutralized using phenolphthalein/ethanol TS, cool, and allow to stand for 15 minutes with frequent shaking. Filter, wash the residue with neutralized 1-propanol R, filter again, and combine the filtrate and the wash liquids. Titrate with sodium hydroxide (0.05 mol/l) VS, using phenolphthalein/ethanol TS as indicator, until a pink colour persists for 15 seconds; not more than 0.15 mL of sodium hydroxide (0.05 mol/l) VS is required.

Assay. Carry out the combustion as described under 2.4 Oxygen flask method for iodine, using about 15 mg, accurately weighed. Titrate the liberated iodine with sodium thiosulfate (0.02 mol/l) VS.

Each mL of sodium thiosulfate (0.02 mol/l) VS is equivalent to 0.7450 mg of $C_{10}H_{11}I_2NO_3$.

Additional requirement for Propyliodone for parenteral use

Complies with the monograph for "Parenteral preparations".