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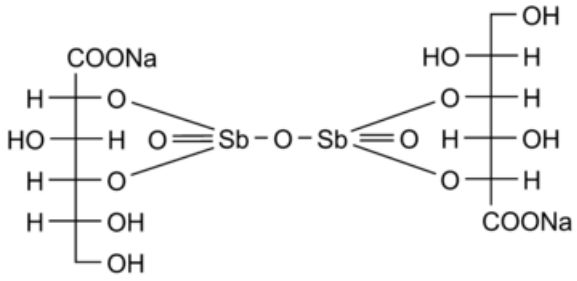
Sodium Stibogluconate

General Notices



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Action and use

Pentavalent antimony compound; antiprotozoal.

Preparation

Sodium Stibogluconate Injection

DEFINITION

Sodium Stibogluconate is mainly the disodium salt of μ-oxy-bis[gluconato(3-)-O^2, O^3,O^4-hydroxoantimony]. It contains not less than 30.0% and not more than 34.0% of antimony(V), calculated with reference to the dried and methanol-free substance.

PRODUCTION

The method of manufacture is such as to ensure consistently controlled reaction stoichiometry in order to yield sodium stibogluconate that is satisfactory with regard to intrinsic toxicity.

CHARACTERISTICS

A colourless, mostly amorphous powder.

Very soluble in *water*; practically insoluble in *ethanol (96%)* and in *ether*.

IDENTIFICATION

A. A solution is dextrorotatory.
B. Pass *hydrogen sulfide* into a 5% w/v solution for several minutes. An orange precipitate is produced.

C. When heated it chars, without melting, leaving a residue which yields the reactions characteristic of *antimony compounds* and the reactions characteristic of *sodium salts*, Appendix VI.

TESTS

Stability and acidity of solution

Heat a solution containing the equivalent of 10% w/v of antimony(V) in an autoclave at 115.5° and at a pressure of 70 kPa for 30 minutes. The resulting solution is colourless or almost colourless and has a pH of 5.0 to 5.6, Appendix V L.

Antimony(III)

Dissolve 2 g in 30 mL of *water*, add 15 mL of *hydrochloric acid* and titrate with *0.00833M potassium bromate VS* using *methyl orange solution* as indicator. Not more than 1.3 mL of *0.00833M potassium bromate VS* is required.

Chloride

Dissolve 2.5 g in 50 mL of *water* and add 2 mL of 2M *nitric acid* and 75 mL of *acetate buffer pH 5.0*. Titrate with *0.1M silver nitrate VS* determining the end point potentiometrically. Not more than 3.0 mL of *0.1M silver nitrate VS* is required.

Methanol

Not more than 2.0% w/w when determined by the following method. Carry out the method for *gas chromatography*, Appendix III B, using the following solutions. For solution (1) add 1 mL of a 1.0% v/v solution of *methanol* to 5 mL of a 0.2% v/v solution of *absolute ethanol* (internal standard). For solution (2) add 5 mL of *water* to 0.5 g of the substance being examined and mix with the aid of ultrasound until solution is complete. For solution (3) add 5 mL of a 0.2% v/v solution of the internal standard to 0.5 g of the substance being examined and mix with the aid of ultrasound until solution is complete.

The chromatographic procedure may be carried out using a glass column (1.5 m × 4 mm) packed with porous polymer beads (80 to 100 mesh) (Porapak Q and Chromosorb 101 are suitable) and maintained at 130°.

Calculate the percentage w/w of methanol taking 0.792 g as its weight per mL at 20°.

Loss on drying

When dried to constant weight at 130° at a pressure not exceeding 0.7 kPa, loses not more than 15.0% of its weight. Use 1 g.

ASSAY

Dissolve 0.16 g in 30 mL of *hydrochloric acid*, add 70 mL of *orthophosphoric acid* and stir carefully until completely mixed. Titrate with 0.05M *ammonium iron(II) sulfate VS* prepared using *sulfuric acid (1%)* and determining the end point potentiometrically using a platinum electrode and a silver-silver chloride reference electrode. Each mL of 0.05M *ammonium iron(II) sulfate VS* is equivalent to 3.044 mg of antimony(V).