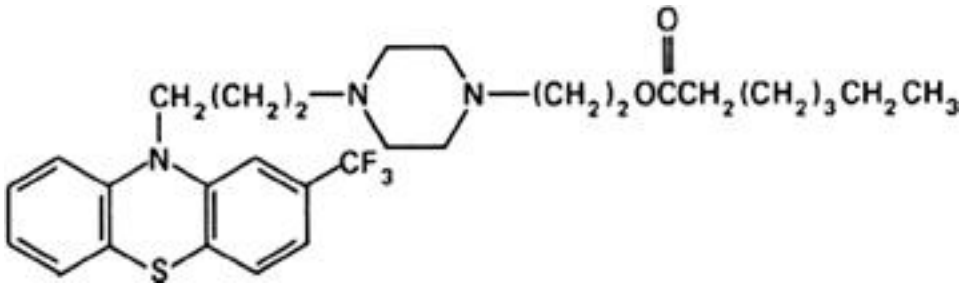
Fluphenazine enantate (Fluphenazini enantas)

Molecular formula. $C_{29}H_{38}F_3N_3O_2S$

Relative molecular mass. 549.7

Graphic formula.



Chemical name. 4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazineethanol heptanoate (ester); 4-[3-[2-(trifluoromethyl)-10*H*-phenothiazin-10-yl]propyl]-1-piperazineethanol heptanoate (ester); CAS Reg. No. 2746-81-8.

Description. A pale yellow, viscous liquid or a yellow, crystalline, oily solid; odour, faint, ester-like.

Miscibility. Immiscible with water; miscible with dehydrated ethanol R and ether R.

Category. Neuroleptic.

Storage. Fluphenazine enantate should be kept in a well-closed container, protected from light.

Requirements

Definition. Fluphenazine enantate contains not less than 98.5% and not more than 101.5% of $C_{29}H_{38}F_3N_3O_2S$, 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 fluphenazine enantate RS or with the *reference spectrum* of fluphenazine enantate.

B. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R2 as the coating substance and a mixture of 5 volumes of *n*-tetradecane R and 95 volumes of hexane R to impregnate the plate, dipping it about 5 mm beneath the surface of the liquid. After the solvent has reached the top of the plate, remove the plate from the chromatographic chamber and allow it to stand at room temperature until the solvents have completely evaporated. Use the impregnated plate immediately, carrying out the chromatography in the same direction as the impregnation. As the mobile phase, use a mixture of 90 volumes of methanol R and 10 volumes of water. Apply separately to the plate 1 µl of each of 2 solutions in ethanol (~750 g/l) TS containing (A) 20 mg of the test substance per mL and (B) 20 mg of fluphenazine enantate RS per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254 nm). The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

C. Dissolve 5 mg in 2 mL of sulfuric acid (~1760 g/l) TS and allow to stand for 5 minutes; a reddish brown colour is produced.

Sulfated ash. Not more than 2.0 mg/g.

Loss on drying. Dry to constant weight at 60°C under reduced pressure (not exceeding 0.6 kPa or about 5 mm of mercury); it loses not more than 10 mg/g.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R2 as the coating substance and a mixture of 80 volumes of acetone R, 30 volumes of cyclohexane R, and 5 volumes of ammonia (~260 g/l) TS as the mobile phase. Apply separately to the plate 20 µl of each of 2 solutions in methanol R containing (A) 25 mg of the test substance per mL and (B) 0.25 mg of fluphenazine hydrochloride RS per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254 nm). Then spray the plate with sulfuric acid (~635 g/l) TS and examine the chromatogram in daylight. Using either method of visualization, any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay. Dissolve about 0.55 g, accurately weighed, in 30 mL of glacial acetic acid R1, and titrate with perchloric acid (0.1 mol/l)

VS, as described under 2.6 Non-aqueous titration. Method A. Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 27.49 mg of $C_{29}H_{38}F_3N_3O_2S$.

Additional requirement for Fluphenazine enantate for parenteral use

Complies with the monograph for "Parenteral preparations".