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Fluphenazine Decanoate

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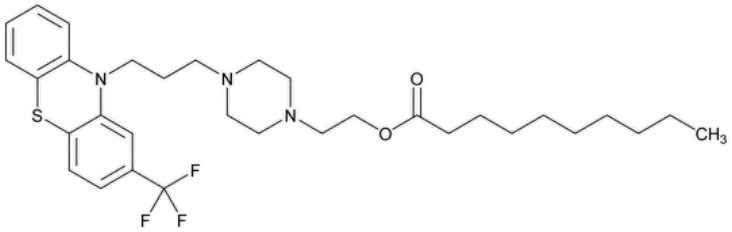

$C_{32}H_{44}F_3N_3O_2S$ ▲591.78▲ (CN 1-May-2024)

Decanoic acid, 2-[4-[3-[2-(trifluoromethyl)-10*H*-decanoate phenothiazin-10-yl]propyl]-1-piperazinyl]ethyl ester;

2-[4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazinyl]ethyl decanoate CAS RN®: 5002-47-1; UNII: FMU62K1L3C.

DEFINITION

Fluphenazine Decanoate contains NLT 98.0% and NMT 102.0% of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$), calculated on the dried basis.

[NOTE—Throughout the following procedures, protect samples, the Reference Standard, and solutions containing them by conducting the procedures without delay under subdued light, or using low-actinic glassware.]

IDENTIFICATION

• **A. INFRARED ABSORPTION**

Solution A: Sodium hydroxide solution (1 in 250)

Standard solution: Transfer 50 mg of USP Fluphenazine Decanoate Dihydrochloride RS to a glass-stoppered, small centrifuge tube, and add 1.5 mL of *Solution A*. Add 2 mL of carbon disulfide, shake vigorously for 2 min, and centrifuge. Dry the lower, clear layer by filtering through 2 g of anhydrous sodium sulfate. Use the filtrate.

Sample solution: Transfer 50 mg of Fluphenazine Decanoate to a glass-stoppered, small centrifuge tube, and add 1.5 mL of *Solution A*. Add 2 mL of carbon disulfide, shake vigorously for 2 min, and centrifuge. Dry the lower, clear layer by filtering through 2 g of anhydrous sodium sulfate. Use the filtrate.

Instrumental conditions

Mode: IR

Cell: 0.1 mm

Acceptance criteria: The absorption spectrum of the *Sample solution* exhibits maxima only at the same wavelengths as that of the *Standard solution*.

• **B. THIN-LAYER CHROMATOGRAPHY**

Standard solution: 22.5 mg/mL of USP Fluphenazine Decanoate Dihydrochloride RS (equivalent to 20 mg/mL of fluphenazine decanoate) in alcohol

Sample solution: 20 mg/mL of Fluphenazine Decanoate in alcohol

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture. Impregnate the plate with a 1-in-20 solution of tetradecane in hexane, and allow to air-dry.

Application volume: 1 µL

Developing solvent system: Methanol and water (90:10)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Standard solution* and the *Sample solution* to the plate. Allow the spots to dry. Apply 1.0 µL of 0.1 N sodium hydroxide to the spot from the *Standard solution*, and allow it to dry. Develop the plate in an equilibrated chamber using the *Developing solvent system*. Examine the plate under short-wavelength UV light at 254 nm.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **PROCEDURE**

Sample: 500 mg of Fluphenazine Decanoate

Blank: 50 mL of glacial acetic acid

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid, add one drop of crystal violet TS, and titrate with *Titrant* to a blue-green endpoint. Perform the *Blank* determination, and make any necessary correction.

Calculate the percentage of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$) in the portion of Fluphenazine Decanoate taken. Each mL of 0.1 N perchloric acid is equivalent to 29.59 mg of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$).

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

• **Ordinary Impurities ⟨466⟩**

Test solution and **Standard solution:** Methanol

Eluant: Acetone, cyclohexane, and ammonium hydroxide (16:6:1)

Visualization: 1; then spray the plate with 50% sulfuric acid.

Acceptance criteria

Individual impurity: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry under vacuum at 60° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Fluphenazine Decanoate Dihydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
FLUPHENAZINE DECANOATE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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