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Fluphenazine Decanoate Injection

DEFINITION

Fluphenazine Decanoate Injection is a sterile solution of Fluphenazine Decanoate in a suitable vegetable oil. It contains NLT 90.0% and NMT 115.0% of the labeled amount of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$).

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

IDENTIFICATION

• **A.**

Solution A: Palladium chloride solution (1 in 1000)

Sample: Nominally 50 mg of fluphenazine decanoate from Injection

Analysis

Part 1: Add 2 mL of methanol and 3 mL of *Solution A* to the *Sample*.

Part 2: Add an excess of *Solution A* to the resulting mixture from *Part 1*.

Acceptance criteria: The criteria for *Part 1* and *Part 2* must both be met.

Part 1: A rust-red color is produced.

Part 2: The color is intensified to a brownish red.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Mobile phase: Acetonitrile, methanol, and 0.05 M ammonium acetate (2:2:1)

Diluent: Acetonitrile and methanol (50:50)

System suitability stock solution: USP Fluphenazine Decanoate Dihydrochloride RS and USP Fluphenazine Hydrochloride RS (5:4) in *Diluent*

System suitability solution: 0.1 mg/mL of anhydrous fluphenazine decanoate dihydrochloride and 0.08 mg/mL of fluphenazine hydrochloride from *System suitability stock solution* in *Diluent*

Standard stock solution A: 0.1 mg/mL of USP Fluphenazine Hydrochloride RS in isopropyl alcohol

Standard stock solution B: 0.5 mg/mL of USP Fluphenazine Decanoate Dihydrochloride RS and 0.02 mg/mL of fluphenazine hydrochloride from *Standard stock solution A* prepared as follows. Transfer 25 mg of USP Fluphenazine Decanoate Dihydrochloride RS to a 50-mL volumetric flask, and add 10 mL of *Standard stock solution A*. Add 20 mL of isopropyl alcohol. Sonication may be used to aid in dissolution. Dilute with isopropyl alcohol to volume.

Standard solution: 0.1 mg/mL of fluphenazine decanoate and 0.004 mg/mL of fluphenazine hydrochloride from *Standard stock solution B* in acetonitrile

Sample stock solution: Nominally 0.5 mg/mL of fluphenazine decanoate in isopropyl alcohol prepared as follows. Transfer a quantity of Injection, equivalent to 25 mg of fluphenazine decanoate, to a 50-mL volumetric flask. Add 20 mL of isopropyl alcohol, and shake vigorously for at least 1 min. Add 20 mL more of isopropyl alcohol, and repeat the vigorous shaking. Dilute with isopropyl alcohol to volume.

Sample solution: Nominally 0.1 mg/mL of fluphenazine decanoate from *Sample stock solution* in acetonitrile

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Columns

Guard: 4.6-mm × 5-cm; 30- to 40-µm packing L1

Analytical: 4.6-mm × 25-cm; 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

Run time: 2.5 times the retention time of fluphenazine decanoate

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for fluphenazine and fluphenazine decanoate are about 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between fluphenazine and fluphenazine decanoate, *System suitability solution*

Relative standard deviation: NMT 2.0% for fluphenazine decanoate, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of fluphenazine decanoate from the *Sample solution*

r_S = peak response of fluphenazine decanoate from the *Standard solution*

C_S = concentration of USP Fluphenazine Decanoate Dihydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of fluphenazine decanoate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of fluphenazine decanoate, ▲591.78▲ (CN 1-May-2024)

M_{r2} = molecular weight of fluphenazine decanoate dihydrochloride, ▲664.69▲ (CN 1-May-2024)

Acceptance criteria: 90.0%–115.0%

IMPURITIES

Change to read:

• **Limit of Fluphenazine and Late-Eluting Impurities**

Analysis: Using the chromatograms from the *Assay*, calculate the percentage of fluphenazine in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak height of fluphenazine from the *Sample solution*

r_S = peak height of fluphenazine from the *Standard solution*

C_S = concentration of USP Fluphenazine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of fluphenazine decanoate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of fluphenazine, ▲437.53▲ (CN 1-May-2024)

M_{r2} = molecular weight of fluphenazine hydrochloride, 510.44

Calculate the percentage of each impurity eluting after fluphenazine decanoate in the portion of Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak height of each impurity eluting after fluphenazine decanoate from the *Sample solution*

r_T = sum of the peak heights of fluphenazine decanoate and all the impurities eluting after fluphenazine decanoate from the *Sample solution*

Acceptance criteria

Fluphenazine: NMT 4%

Total impurities eluting after fluphenazine decanoate: NMT 2%

SPECIFIC TESTS

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Fluphenazine Hydrochloride RS

USP Fluphenazine Decanoate Dihydrochloride RS

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

Chromatographic Database Information: Chromatographic Database

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