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Fluphenazine Hydrochloride Oral Solution

DEFINITION

Fluphenazine Hydrochloride Oral Solution is an aqueous solution of Fluphenazine Hydrochloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$).

[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. Thin-Layer Chromatography**

Diluent: Methanol and water (80:20)

Standard solution: 20 mg/mL of USP Fluphenazine Hydrochloride RS in *Diluent* prepared as follows. Transfer 10 mg of USP Fluphenazine Hydrochloride RS to a separator, and add 20 mL of sodium hydroxide solution (1 in 4). Extract the resulting mixture with 20 mL of isooctane. Evaporate the isooctane solution to dryness, and dissolve the residue in 0.5 mL of *Diluent*.

Sample solution: Nominally 20 mg/mL of fluphenazine hydrochloride from Oral Solution in *Diluent* prepared as follows. Transfer a volume of Oral Solution, equivalent to 10 mg of fluphenazine hydrochloride, to a separator, and add 20 mL of sodium hydroxide solution (1 in 4). Extract the resulting mixture with 20 mL of isooctane. Evaporate the isooctane solution to dryness, and dissolve the residue in 0.5 mL of *Diluent*.

Chromatographic system

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

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Acetone, cyclohexane, and diethylamine (40:15:1)

Spray reagent: Sulfuric acid in methanol (2 in 5)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the spots to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Locate the spots on the plate by lightly spraying it with *Spray reagent*.

Acceptance criteria: The R_F value and color of the principal spot of the *Sample solution* correspond to those of the *Standard solution*.

ASSAY

• **Procedure**

Buffer: 0.05 M monobasic potassium phosphate adjusted with phosphoric acid to a pH of 2.5

Diluent: Acetonitrile, methanol, and *Buffer* (30:30:40)

Mobile phase: 0.2% triethylamine in *Diluent*

Standard solution: 0.06 mg/mL of USP Fluphenazine Hydrochloride RS in *Diluent*

Sample solution: Nominally 0.06 mg/mL of fluphenazine hydrochloride from Oral Solution in *Diluent* prepared as follows. Transfer a suitable volume of Oral Solution, equivalent to 6 mg of fluphenazine hydrochloride, to a 100-mL volumetric flask using a “to contain” pipet. Rinse the pipet with *Diluent* to complete the transfer, and dilute with *Diluent* to volume. Filter, and use the filtrate after discarding the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 12.5-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$) in the portion of Oral Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **Alcohol Determination ⟨611⟩:** 90.0%–110.0% of the labeled amount, the labeled amount being NMT 15.0% of alcohol (C_2H_5OH)

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light.

• **Labeling:** Label it to indicate that it is to be diluted to appropriate strength with water or other suitable fluid prior to administration.

• **USP Reference Standards ⟨11⟩**

USP Fluphenazine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
FLUPHENAZINE HYDROCHLORIDE ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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