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Fluphenazine Hydrochloride Injection

DEFINITION

Fluphenazine Hydrochloride Injection is a sterile solution of Fluphenazine Hydrochloride in Water for Injection. It contains NLT 95.0% 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 6 N sodium hydroxide. 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 Injection in *Diluent* prepared as follows. Transfer a volume of Injection, equivalent to 10 mg of fluphenazine hydrochloride, to a separator, and add 20 mL of 6 N sodium hydroxide. 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 Injection in *Diluent* prepared as follows. Transfer a suitable volume of Injection, 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 Injection 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: 95.0%–110.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 4.8–5.2
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 166.7 USP Endotoxin Units/mg of fluphenazine hydrochloride
- **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, and protect from light.
- **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 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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