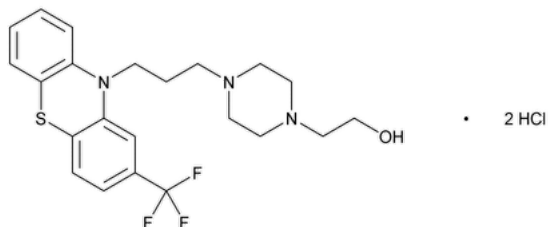


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Fluphenazine Hydrochloride



$C_{22}H_{26}F_3N_3OS \cdot 2HCl$ 510.44

1-Piperazineethanol, 4-[3-[2-(trifluoromethyl)-10H-phenothiazin-10-yl]propyl]-, dihydrochloride;

4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1- piperazineethanol dihydrochloride CAS RN®: 146-56-5; UNII: ZOU145W1XL.

DEFINITION

Fluphenazine Hydrochloride contains NLT 97.0% and NMT 103.0% of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$), 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

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

Change to read:

- **B.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U ▲](#) (CN 1-MAY-2020)

Analytical wavelength: 259 nm

Sample solution: 10 µg/mL of Fluphenazine Hydrochloride in methanol

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 2.5%.

- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\):](#) Meets the requirements

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 stock solution: 1.2 mg/mL of Fluphenazine Hydrochloride in *Diluent*

Sample solution: 0.06 mg/mL of Fluphenazine Hydrochloride from *Sample stock solution* in *Diluent*. Filter, and discard 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 fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$) in the portion of Fluphenazine Hydrochloride 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 = concentration of Fluphenazine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

• [ORDINARY IMPURITIES \(466\)](#)

Standard solution and **Test solution:** 0.1 M methanolic sodium hydroxide

Eluant: Acetone, cyclohexane, and diethylamine (40:15:1)

Visualization: 1

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 65° for 3 h.

Acceptance criteria: NMT 1%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [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	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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