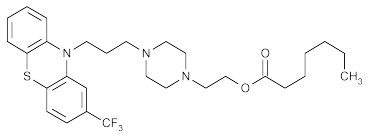
of fluphenazine decanoate ($C_{32}H_{44}F_3N_3O_2S$) in each mL of the Injection taken by the formula:

$$0.890(W_S / W_U)(r_U / r_S)$$

in which W_S is the weight, in mg, of USP Fluphenazine Decanoate Dihydrochloride RS corrected for its moisture content, used to prepare the *Standard preparation*; W_U is the volume, in mL, of *Injection* taken, and r_U and r_S are the peak responses of fluphenazine decanoate obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Fluphenazine Enanthate



$C_{29}H_{38}F_3N_3O_2S$ 549.69
Heptanoic acid, 2-[4-[3-[2-(trifluoromethyl)-10*H*-phenothiazin-10-yl]propyl]-1-piperazinyl]ethyl ester.
2-[4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazinyl]ethyl heptanoate [2746-81-8].

» Fluphenazine Enanthate contains not less than 97.0 percent and not more than 103.0 per cent of $C_{29}H_{38}F_3N_3O_2S$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Fluphenazine Enanthate Dihydrochloride RS
$C_{29}H_{38}F_3N_3O_2S \cdot 2HCl$ 622.63

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

Identification—

A: Place about 50 mg of Fluphenazine Enanthate and about 50 mg of USP Fluphenazine Enanthate Dihydrochloride RS in separate, glass-stoppered, small centrifuge tubes, and treat each tube as follows. Add 1.5 mL of sodium hydroxide solution (1 in 250), and mix. Add 2 mL of carbon disulfide, shake vigorously for 2 minutes, and centrifuge. Dry the lower, clear layer by filtering it through 2 g of anhydrous sodium sulfate: the IR absorption spectrum of the test preparation, determined in a 0.1-mm cell, exhibits maxima only at the same wavelengths as that of the Standard preparation, similarly measured.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 10 µg per mL.

Medium: methanolic hydrochloric acid (8.5 in 1000).

Absorptivities at 258 nm, calculated on the dried basis, do not differ by more than 2.5%.

Loss on drying ⟨731⟩—Dry it in vacuum at 60 ° for 3 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.2%.

Heavy metals, *Method II* ⟨231⟩: 0.003%.

Ordinary impurities ⟨466⟩**—**

Test solution: alcohol.

Standard solution: alcohol.

Eluant: a mixture of alcohol, glacial acetic acid, and water (3:1:1).

Visualization: 1.

Assay—Dissolve about 500 mg of Fluphenazine Enanthate, accurately weighed, in 50 mL of glacial acetic acid, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a blue-green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 27.49 mg of $C_{29}H_{38}F_3N_3O_2S$.

Fluphenazine Enanthate Injection

» Fluphenazine Enanthate Injection is a sterile solution of Fluphenazine Enanthate in a suitable vegetable oil. It contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of fluphenazine enanthate ($C_{29}H_{38}F_3N_3O_2S$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I or Type III glass, protected from light.

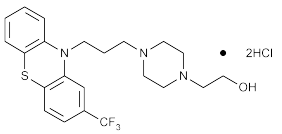
NOTE—Throughout the following procedures, protect test or assay specimens, the USP Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

Identification—To a volume of Injection, equivalent to about 50 mg of fluphenazine enanthate, add 2 mL of methanol and 3 mL of palladium chloride solution (1 in 1000): a rust-red color is produced. Add an excess of the palladium chloride solution: the color is intensified to a brownish red.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—Dissolve an accurately measured volume of Injection, equivalent to about 150 mg of fluphenazine enanthate, in 75 mL of glacial acetic acid, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a blue-green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 27.49 mg of fluphenazine enanthate ($C_{29}H_{38}F_3N_3O_2S$).

Fluphenazine Hydrochloride



$C_{22}H_{26}F_3N_3OS \cdot 2HCl$ 510.44
1-Piperazineethanol, 4-[3-[2-(trifluoromethyl)-10*H*-phenothiazin-10-yl]propyl]-, dihydrochloride.
4-[3-[2-(Trifluoromethyl)phenothiazin-10-yl]propyl]-1-piperazineethanol dihydrochloride [146-56-5].

» Fluphenazine Hydrochloride contains not less than 97.0 percent and not more than 103.0 percent of $C_{22}H_{26}F_3N_3OS \cdot 2HCl$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Fluphenazine Hydrochloride RS

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

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 10 µg per mL.

Medium: methanol.

Absorptivities at 259 nm, calculated on the dried basis, do not differ by more than 2.5%.

C: A solution of Fluphenazine Hydrochloride responds to the tests for *Chloride* ⟨191⟩.

Loss on drying ⟨731⟩**—**Dry it at 65 ° for 3 hours: it loses not more than 1% of its weight.

Residue on ignition ⟨281⟩: not more than 0.5%.

Heavy metals, *Method II* ⟨231⟩: 0.003%.

Ordinary impurities ⟨466⟩**—**

Test solution: 0.1 M methanolic sodium hydroxide.

Standard solution: 0.1 M methanolic sodium hydroxide.

Eluant: a mixture of acetone, cyclohexane, and diethylamine (40:15:1).

Visualization: 1.

Assay—

Diluent solution—Prepare a filtered and degassed mixture of 0.05 M monobasic potassium phosphate (adjusted with phosphoric acid to a pH of 2.5), acetonitrile, and methanol (40:30:30). Make adjustments if necessar y (see *System Suitability* under *Chromatography* ⟨621⟩).

Mobile phase—Prepare a mixture containing 0.2% triethylamine in *Diluent solution*.

Standard preparation—Dissolve an accurately weighed quantity of USP Fluphenazine Hydrochloride RS in *Diluent solution*, and dilute quantitatively, and stepwise if necessar y, with *Diluent solution* to obtain a solution having a known concentration of about 0.06 mg per mL.

Assay preparation—Transfer about 120 mg of Fluphenazine Hydrochloride, accurately weighed, to a 100-mL volumetric flask. Dissolve in and dilute with *Diluent solution* to volume, and mix. Pipet 5.0 mL of this solution into a 100-mL volumetric flask, dilute with *Diluent solution* to volume, and mix. Filter, discarding the first 5 mL of the filtrate.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 12.5-cm column that contains packing L7. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure :* the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{22}H_{26}F_3N_3OS \cdot 2HCl$ in the portion of Fluphenazine Hydrochloride taken by the formula:

$$2000C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Fluphenazine Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Fluphenazine Hydrochloride Elixir

» Fluphenazine Hydrochloride Elixir contains not less than 90.0 per cent and not more than 110.0 percent of the labeled amount of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$).

Packaging and storage—Preserve in tight containers, protected from light.

USP Reference standards ⟨11⟩**—**
USP Fluphenazine Hydrochloride RS

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

Identification—Transfer a volume of Elixir, equivalent to about 10 mg of fluphenazine hydrochloride, to a separator, and to a second separator transfer 10 mg of USP Fluphenazine Hydrochloride RS. To each separator add 20 mL of 6 N sodium hydroxide, and extract each mixture with 20 mL of isooctane. Evaporate the isooctane solutions to dr yness, and proceed as directed in the *Identification* test under *Fluphenazine Hydrochloride Tablets,* beginning with "dissolve the residues in 0.5-mL portions."

Uniformity of dosage units ⟨905⟩**—**

FOR ELIXIR PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩**—**

FOR ELIXIR PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

pH ⟨791⟩**:** between 5.3 and 5.8.

Alcohol content ⟨611⟩**:** not less than 90.0% and not more than 110.0% of the labeled amount, the labeled amount being not more than 15.0% of C_2H_5OH.

Assay—

Diluent solution, Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Fluphenazine Hydrochloride*.

Assay preparation—Using a "to contain" pipet transfer a volume of Elixir, equivalent to about 6 mg of fluphenazine hydrochloride, to a 100-mL volumetric flask. Rinse the pipet with *Diluent solution* to complete the transfer, dilute with *Diluent solution* to volume, and mix. Filter, discarding the first 5 mL of the filtrate.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$) in each mL of the Elixir taken by the formula:

$$100(C/V)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Fluphenazine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Elixir taken; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Fluphenazine Hydrochloride Injection

» Fluphenazine Hydrochloride Injection is a sterile solution of Fluphenazine Hydrochloride in W ater for Injection. It contains not less than 95.0 per cent and not more than 110.0 per cent of the labeled amount of fluphenazine hydrochloride ($C_{22}H_{26}F_3N_3OS \cdot 2HCl$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of T ype I glass, protected from light.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Fluphenazine Hydrochloride RS