Flurazepam Hydrochloride

\[ \text{C}_{21}\text{H}_{23}\text{ClF}_{2}\text{N}_{2}\text{O}.\text{HCl}: \text{424.34} \]
7-Chloro-1-[2-(diethylamino)ethyl]-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one monohydrochloride [36105-20-1]

Flurazepam Hydrochloride, when dried, contains not less than 99.0% of \( \text{C}_{21}\text{H}_{23}\text{ClF}_{2}\text{N}_{2}\text{O}.\text{HCl} \).

**Description** Flurazepam Hydrochloride occurs as white to yellowish white crystals or crystalline powder.
- It is freely soluble in water, in ethanol (95), in ethanol (99.5) and in acetic acid (100).
- Melting point: about 197°C (with decomposition).

**Identification** (1) Determine the absorption spectrum of a solution of Flurazepam Hydrochloride in sulfuric acid-water (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.
- (2) Determine the infrared absorption spectrum of Flurazepam Hydrochloride, previously dried, as directed in the potassium chloride disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.
- (3) A solution of Flurazepam Hydrochloride (1 in 20) responds to the Qualitative Tests for chloride.

**pH** Dissolve 1.0 g of Flurazepam Hydrochloride in 20 mL of water: the pH of this solution is between 5.0 and 6.0.

**Purity** (1) Clarity and color of solution—Dissolve 1.0 g of Flurazepam Hydrochloride in 10 mL of water: the solution is clear and colorless to pale yellow.
- (2) Sulfate—Perform the test with 1.5 g of Flurazepam Hydrochloride. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.011%).
- (3) Heavy metals—Proceed with 1.0 g of Flurazepam Hydrochloride in a platinum crucible according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).
- (4) Related substances—Dissolve 0.05 g of Flurazepam Hydrochloride in 5 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add ethanol (95) to make exactly 50 mL. Pipet 1 mL of this solution, add ethanol (95) to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Place the plate in a chamber filled with ammonia vapor, allow to stand for about 15 minutes, and immediately develop the plate with a mixture of diethyl ether and diethylamine (39:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): not more than 3 spots other than the principal spot and the spot on the starting point from the sample solution appear, and are not more intense than the spot from the standard solution.

**Loss on drying** Not more than 0.5% (1 g, 105°C, 4 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.3 g of Flurazepam Hydrochloride, previously dried, dissolve in 10 mL of acetic acid (100), add 40 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 21.217 mg of \( \text{C}_{21}\text{H}_{23}\text{ClF}_{2}\text{N}_{2}\text{O}.\text{HCl} \)

**Containers and storage** Containers—Tight containers.

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**Flurbiprofen**

フールビプロフェン

\[ \text{C}_{13}\text{H}_{17}\text{FO}_{2}: \text{244.26} \]
\((\text{RS})-2-(2-\text{Fluorobiphenyl}-4-\text{yl})\text{propanoic acid} [5104-69-4]\)

Flurbiprofen, when dried, contains not less than 98.0% of \( \text{C}_{13}\text{H}_{17}\text{FO}_{2} \).

**Description** Flurbiprofen occurs as a white, crystalline powder. It has a slightly irritating odor.
- It is freely soluble in methanol, in ethanol (95), in acetone and in diethyl ether, soluble in acetonitrile, and practically insoluble in water.
- A solution of Flurbiprofen in ethanol (95) (1 in 50) shows no optical rotation.

**Identification** (1) Determine the absorption spectrum of a solution of Flurbiprofen in methanol (1 in 200,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.
- (2) Determine the infrared absorption spectrum of Flurbiprofen, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

**Melting point** 114 - 117°C