

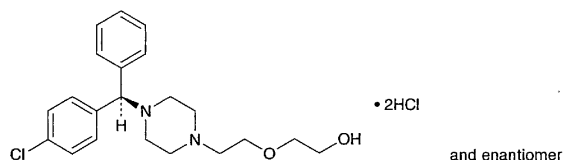
water to make exactly 50 mL. To 2 mL of this solution, exactly measured, add acetic acid-sodium acetate buffer solution, pH 5.0, to make exactly 50 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , of the sample solution and the standard solution at 361 nm as directed under the Ultraviolet-visible Spectrophotometry.

Amount (mg) of $C_{62}H_{89}CoN_{13}O_{15}P \cdot C_2H_4O_2$
 = amount (mg) of Cyanocobalamin Reference Standard,
 calculated on the dried basis
 $\times \frac{A_T}{A_S} \times 1.0377$

Containers and storage Containers—Tight containers.
 Storage—Light-resistant, and in a cold place.

Hydroxyzine Hydrochloride

塩酸ヒドロキシジン



$C_{21}H_{27}ClN_2O_2 \cdot 2HCl$: 447.83
 2-(2-{4-[(*RS*)-(4-Chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy)ethanol dihydrochloride [2192-20-3]

Hydroxyzine Hydrochloride, when dried, contains not less than 98.5% of $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$.

Description Hydroxyzine Hydrochloride occurs as a white, crystalline powder. It is odorless, and has a bitter taste.

It is very soluble in water, freely soluble in methanol, in ethanol (95) and in acetic acid (100), very slightly soluble in acetic anhydride, and practically insoluble in diethyl ether.

Melting point: about 200°C (with decomposition).

Identification (1) To 5 mL of a solution of Hydroxyzine Hydrochloride (1 in 100) add 2 to 3 drops of ammonium thiocyanate-cobaltous nitrate TS: a blue precipitate is formed.

(2) Determine the absorption spectrum of a solution of Hydroxyzine Hydrochloride in methanol (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.

(3) A solution of Hydroxyzine Hydrochloride (1 in 10) responds to the Qualitative Tests for chloride.

pH Dissolve 1.0 g of Hydroxyzine Hydrochloride in 20 mL of water: the pH of this solution is between 1.3 and 2.5.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Hydroxyzine Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Hydroxyzine Hydrochloride 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).

(3) Related substances—Dissolve 0.20 g of Hydroxyzine Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μ L each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (95) and ammonia solution (28) (150:95:1) to a distance of about 10 cm, and air-dry the plate. Allow the plate to stand in iodine vapor: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 3.0% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.20% (1 g).

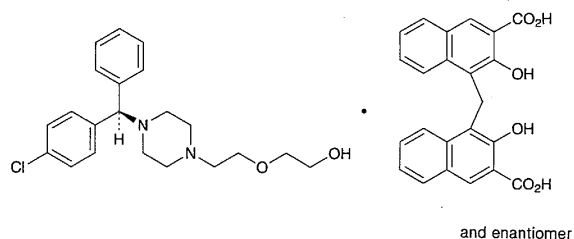
Assay Weigh accurately about 0.1 g of Hydroxyzine Hydrochloride, previously dried, dissolve in 60 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
 = 22.392 mg of $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$

Containers and storage Containers—Tight containers.

Hydroxyzine Pamoate

パモ酸ヒドロキシジン



$C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$: 763.27
 2-(2-{4-[(*RS*)-(4-Chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy)ethanol mono[4,4'-methylenebis(3-hydroxy-2-naphthoate)] (1/1) [10246-75-0]

Hydroxyzine Pamoate contains not less than 98.0% of $C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$, calculated on the anhydrous basis.

Description Hydroxyzine Pamoate occurs as a light yellow, crystalline powder. It is odorless, and has a slightly bitter taste.

It is freely soluble in *N,N*-dimethylformamide, slightly soluble in acetone, and practically insoluble in water, in methanol, in ethanol (95) and in diethyl ether.

Identification (1) To 0.1 g of Hydroxyzine Pamoate add 25 mL of sodium hydroxide TS, and shake well. Extract