

A_T and A_S , of the sample solution and the standard solution, respectively, at 361 nm as directed under the Ultraviolet-visible Spectrophotometry.

$$\begin{aligned} & \text{Amount (mg) of } C_{63}H_{88}CoN_{14}O_{14}P \\ & = \text{amount (mg) of Cyanocobalamin Reference} \\ & \quad \text{Standard, calculated on the dried basis} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Cyanocobalamin Injection

Vitamin B₁₂ Injection

シアノコバラミン注射液

Cyanocobalamin Injection is an aqueous solution for injection. It contains not less than 95% and not more than 115% of the labeled amount of cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$: 1355.37)

Method of preparation Prepare as directed under Injections, with Cyanocobalamin.

Description Cyanocobalamin Injection is a clear, light red to red liquid

It is gradually affected by light.

pH: 4.0 – 5.5

Identification Determine the absorption spectrum of the sample solution obtained in the Assay as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 277 nm and 279 nm, between 360 nm, and 362 nm and between 548 nm and 552 nm. Determine the absorbances, A_1 and A_2 , of this solution at the wavelengths of maximum absorption between 360 nm and 362 nm, and between 548 nm and 552 nm, respectively: the ratio A_2/A_1 is not less than 0.29 and not more than 0.32.

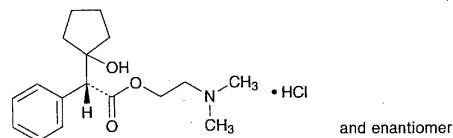
Assay Measure exactly a volume of Cyanocobalamin Injection, equivalent to about 2 mg of cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$), add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.02 g of Cyanocobalamin Reference Standard (previously determine the loss on drying in the same manner as Cyanocobalamin), add water to make exactly 1000 mL, and use this solution as the standard solution. With these solutions, proceed as directed in the Assay under Cyanocobalamin.

$$\begin{aligned} & \text{Amount (mg) of cyanocobalamin } (C_{63}H_{88}CoN_{14}O_{14}P) \\ & = \text{amount (mg) of Cyanocobalamin Reference} \\ & \quad \text{Standard, calculated on the dried basis} \\ & \quad \times \frac{A_T}{A_S} \times \frac{1}{10} \end{aligned}$$

Containers and storage Containers—Hermetic containers, and colored containers may be used.
Storage—Light-resistant.

Cyclopentolate Hydrochloride

塩酸シクロペントラート



$C_{17}H_{25}NO_3 \cdot HCl$: 327.85

2-(Dimethylamino)ethyl (*RS*)-(1-hydroxycyclopentyl)-phenylacetate monohydrochloride [5870-29-1]

Cyclopentolate Hydrochloride, when dried, contains not less than 98.5% of $C_{17}H_{25}NO_3 \cdot HCl$.

Description Cyclopentolate Hydrochloride occurs as a white, crystalline powder. It is odorless, or has a characteristic odor.

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

Identification (1) To 1 mL of a solution of Cyclopentolate Hydrochloride (1 in 100) add 1 mL of Reinecke salt TS: a light red precipitate is formed.

(2) Dissolve 0.2 g of Cyclopentolate Hydrochloride in 2 mL of water, add 2 mL of sodium hydroxide TS, and boil for 1 minute. After cooling, add 2 drops of nitric acid: a phenylacetic acid-like odor is perceptible.

(3) Determine the infrared absorption spectrum of Cyclopentolate 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.

(4) A solution of Cyclopentolate Hydrochloride (1 in 50) responds to the Qualitative Tests for chloride.

pH Dissolve 0.20 g of Cyclopentolate Hydrochloride in 20 mL of water: the pH of this solution is between 4.5 and 5.5.

Melting point 135 – 138°C

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

(2) Heavy metals—Proceed with 1.0 g of Cyclopentolate Hydrochloride according to Method 1, 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 Cyclopentolate Hydrochloride in 10 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add chloroform to make exactly 20 mL. Pipet 1 mL of this solution, add chloroform 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 10 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 2-propanol, *n*-butyl acetate, water and ammonia solution (28)