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Cocaine Hydrochloride Tablets for Topical Solution

» Cocaine Hydrochloride Tablets for Topical Solution contain not less than 91.0 percent and not more than 109.0 percent of the labeled amount of $C_{17}H_{21}NO_4 \cdot HCl$.

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

USP Reference standards ⟨11⟩—

USP Cocaine Hydrochloride RS

Identification—

A: Add 5 drops of chromium trioxide solution (1 in 20) to 5 mL of a filtered solution of Tablets, equivalent to cocaine hydrochloride solution (1 in 50): a yellow precipitate is formed and it redissolves when the mixture is shaken. On the addition of 1 mL of hydrochloric acid, a permanent, yellowish orange, crystalline precipitate is formed.

B: Dissolve a portion of powdered Tablets, equivalent to about 10 mg of cocaine hydrochloride, in 1 mL of water, filter, and add 2 mL of 0.1 N potassium permanganate: a red-purple, crystalline precipitate, which appears brown when collected on a filter, is formed, and it shows characteristic, crystalline aggregates under the low power of a microscope.

C: Add silver nitrate TS, dropwise, to a filtered solution of Tablets, equivalent to cocaine hydrochloride solution (1 in 20): a white precipitate is formed, and it is insoluble in nitric acid.

Disintegration ⟨701⟩: 15 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—Place 1 Tablet in a 100-mL volumetric flask, add 50 mL of water, and shake the flask until the tablet is dissolved. Dilute with water to volume, mix, and filter, discarding the first 20 mL of the filtrate. Dilute a portion of the subsequent filtrate, if necessary, with water to provide a solution containing approximately 80 µg of cocaine hydrochloride per mL. Concomitantly determine the absorbances of this test solution and a Standard solution of USP Cocaine Hydrochloride RS in the same medium having a known concentration of about 80 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 275 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of $C_{17}H_{21}NO_4 \cdot HCl$ in the Tablet by the formula:

$$(T/D)C(A_U/A_S)$$

in which T is the labeled quantity, in mg, of cocaine hydrochloride in the Tablet; D is the concentration, in µg per mL, of cocaine hydrochloride in the test solution, based upon the labeled quantity per Tablet and the extent of dilution; C is the concentration, in µg per mL, of USP Cocaine Hydrochloride RS in the Standard solution; and A_U and A_S are the absorbances of the solution from the Tablet and the Standard solution, respectively.

Assay—Weigh and finely powder not fewer than 20 Tablets. Dissolve an accurately weighed portion of the powder, equivalent to about 60 mg of cocaine hydrochloride, in 10 mL of water, render the solution slightly alkaline with 6 N ammonium hydroxide, and completely extract the cocaine with small successive portions of ether. Evaporate the combined ether extracts on a steam bath to one-half their volume, transfer the remaining liquid to a separator, and wash with three 5-mL portions of water. Shake the water washings with a small portion of ether, and add the ether washing to the combined ether extracts. Add 10.0 mL of 0.05 N sulfuric acid VS to the ether solution, agitate the mixture thoroughly, and draw off the acidified water layer into a beaker. Wash the ether with two small portions of water, add the washings to the acid liquid, and titrate the excess acid with 0.02 N sodium hydroxide VS, using methyl red TS as the indicator. Each mL of 0.05 N sulfuric acid is equivalent to 16.99 mg of $C_{17}H_{21}NO_4 \cdot HCl$.

Topic/Question	Contact	Expert Committee
COCAINE HYDROCHLORIDE TABLETS FOR TOPICAL SOLUTION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

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