(14:14:7:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water 8.0 - 10.0% (0.25 g, direct titration).

Residue on ignition Not more than 0.1% (0.5 g).

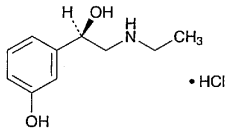
Assay Weigh accurately about 0.5 g of Ethylmorphine Hydrochloride, and dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 34.986 mg of $C_{19}H_{23}NO_3$.HCl

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

Etilefrine Hydrochloride

塩酸エチレフリン



and enantiomer

$C_{10}H_{15}NO_2$.HCl: 217.69
(*RS*)-2-Ethylamino-1-(3-hydroxyphenyl)ethanol monohydrochloride [*943-17-9*]

Etilefrine Hydrochloride, when dried, contains not less than 98.0% of $C_{10}H_{15}NO_2$.HCl.

Description Etilefrine Hydrochloride occurs as white crystals or crystalline powder. It is odorless and has a bitter taste.

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

The pH of a solution of Etilefrine Hydrochloride (1 in 10) is between 3.8 and 5.8.

It is gradually colored by light.

Identification **(1)** To 1 mL of a solution of Etilefrine Hydrochloride (1 in 5000) add 1 mL of a freshly prepared solution of 2,6-dibromoquinonechlorimide in ethanol (95) (1 in 4000) and 5 drops of ammonia TS: a blue color develops.

(2) To 5 mL of a solution of Etilefrine Hydrochloride (1 in 20,000) add 2 mL of a solution of 4-nitrobenzenediazonium fluoroborate (1 in 2000), 5 mL of boric acid-potassium chloride-sodium hydroxide buffer solution, pH 9.2, and 5 mL of acetone: a red color develops.

(3) Dissolve 5 mg of Etilefrine Hydrochloride in 100 mL of diluted hydrochloric acid (1 in 1000). Determine the absorption spectrum of the solution 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.

(4) A solution of Etilefrine Hydrochloride (1 in 1000) responds to the Qualitative Tests for chloride.

Melting point 119 - 124°C

Purity **(1)** Clarity and color of solution—Dissolve 0.5 g of Etilefrine Hydrochloride in 50 mL of water: the solution is clear and colorless.

(2) Sulfate—Perform the test with 0.6 g of Etilefrine Hydrochloride. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.028%).

(3) Heavy metals—Dissolve 1.0 g of Etilefrine Hydrochloride in 30 mL of water and 2 mL of acetic acid (100), adjust with sodium hydroxide TS to a pH of 3.3, add water to make 50 mL, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of Etilefrine Hydrochloride, according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

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

Assay Weigh accurately about 0.3 g of Etilefrine Hydrochloride, previously dried, dissolve in 25 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.

Each mL of 0.1 mol/L perchloric acid VS
= 21.770 mg of $C_{10}H_{15}NO_2$.HCl

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

Etilefrine Hydrochloride Tablets

塩酸エチレフリン錠

Etilefrine Hydrochloride Tablets contain not less than 93% and not more than 107% of the labeled amount of etilefrine hydrochloride ($C_{10}H_{15}NO_2$.HCl: 217.69).

Method of preparation Prepare as directed under Tablets, with Etilefrine Hydrochloride.

Identification **(1)** To a quantity of powdered Etilefrine Hydrochloride Tablets, equivalent to 5 mg of Etilefrine Hydrochloride according to the labeled amount, add 25 mL of water, and filter. Proceed with 1 mL of the filtrate as directed in the Identification (1) under Etilefrine Hydrochloride.

(2) Dilute 5 mL of the filtrate obtained in (1) with water to make 20 mL. Proceed with 5 mL of this solution as directed in the Identification (2) under Etilefrine Hydrochloride.

(3) To a quantity of powdered Etilefrine Hydrochloride Tablets, equivalent to 5 mg of Etilefrine Hydrochloride according to the labeled amount, add 60 mL of diluted hydrochloric acid (1 in 1000), shake well, add 40 mL of diluted hydrochloric acid (1 in 1000), and filter. Determine the absorption spectrum of the filtrate as directed under the Ultraviolet-visible Spectrophotometry, using diluted hydrochloric