

add methanol to make exactly 20 mL. Pipet 4 mL of this solution, add methanol to make exactly 50 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 diethyl ether, methanol and ammonia solution (28) (100:5:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly bismuth nitrate-potassium iodide TS on the plate: 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 1.0% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.4 g of Mepivacaine Hydrochloride, previously dried, dissolve in 10 mL of acetic acid (100) and add 70 mL of acetic anhydride. 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
= 28.281 mg of $C_{15}H_{22}N_2O.HCl$

Containers and storage Containers—Tight containers.

Mepivacaine Hydrochloride Injection

塩酸メピバカイン注射液

Mepivacaine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of mepivacaine hydrochloride ($C_{15}H_{22}N_2O.HCl$: 282.81).

Method of preparation Prepare as directed under Injections, with Mepivacaine Hydrochloride.

Description Mepivacaine Hydrochloride Injection is a clear, colorless liquid.

pH: 4.5 – 6.8

Identification To a volume of Mepivacaine Hydrochloride Injection, equivalent to 0.02 g of Mepivacaine Hydrochloride according to the labeled amount, add 1 mL of sodium hydrochloride TS, and extract with 20 mL of hexane. To 8 mL of the hexane extract add 20 mL of 1 mol/L hydrochloric acid TS, shake vigorously, and determine the absorption spectrum of the water layer separated as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 261 nm and 265 nm, and between 270 nm and 273 nm.

Assay To an exactly measured volume of Mepivacaine Hydrochloride Injection, equivalent to about 0.04 g of Mepivacaine Hydrochloride according to the labeled amount, add exactly 4 mL of the internal standard solution and 0.001 mol/L hydrochloric acid TS to make 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.04 g of mepivacaine hydrochloride for assay, previously dried at 105°C for 3 hours, dissolve in 0.001

mol/L hydrochloric acid TS, add exactly 4 mL of the internal standard solution and 0.001 mol/L hydrochloric acid TS to make 20 mL, and use this solution as the standard solution. Perform the test with 5 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S , of the peak area of mepivacaine to that of the internal standard.

Amount (mg) of $C_{15}H_{22}N_2O.HCl$
= amount (mg) of mepivacaine hydrochloride for assay
 $\times \frac{Q_T}{Q_S}$

Internal standard solution—A solution of benzophenone in methanol (1 in 4000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (10 μ m in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 2.88 g of sodium lauryl sulfate in 1000 mL of a mixture of 0.02 mol/L phosphate buffer solution, pH 3.0 and acetonitrile (11:9).

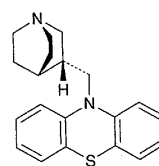
Flow rate: Adjust the flow rate so that the retention time of mepivacaine is about 6 minutes.

Selection of column: Proceed with 5 μ L of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of mepivacaine and benzophenone in this order with the resolution between these peaks being not less than 6.

Containers and storage Containers—Hermetic containers.

Mequitazine

メキタジン



and enantiomer

$C_{20}H_{22}N_2S$: 322.47

10-[(*RS*)-1-Azabicyclo[2.2.2]oct-3-ylmethyl]-10*H*-phenothiazine [29216-28-2]

Mequitazine, when dried, contains not less than 98.5% of $C_{20}H_{22}N_2S$.

Description Mequitazine occurs as white crystals or crystalline powder.

It is freely soluble in methanol and in acetic acid (100), soluble in ethanol (95), and practically insoluble in water.

It is gradually colored by light.

A solution of Mequitazine in methanol (1 in 50) shows no