It is freely soluble in formic acid, soluble in water, sparingly soluble in methanol, and slightly soluble in ethanol (95).

It dissolves in dilute sodium hydroxide TS.

It is affected by light.

Identification (1) Determine the absorption spectrum of a solution of Morphine Hydrochloride (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 1: both spectra exhibit similar intensities of absorption at the same wavelengths. Separately, determine the absorption spectrum of a solution of Morphine Hydrochloride in dilute sodium hydroxide TS (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 2: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Morphine Hydrochloride as directed in the potassium bromide 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.

(3) A solution of Morphine Hydrochloride (1 in 50) responds to the Qualitative Tests (2) for chloride.

Optical rotation $[\alpha]_D^{20}$: -111 - $-116°$ (0.5 g calculated on the anhydrous basis, water, 25 mL, 100 mm).

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Morphine Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Acid—Dissolve 0.5 g of Morphine Hydrochloride in 15 mL of water, add 2 drops of methyl red TS, and neutralize with 0.02 mol/L sodium hydroxide VS: the consumed volume is not more than 0.50 mL.

(3) Ammonium—Warm 0.20 g of Morphine Hydrochloride with 5 mL of sodium hydroxide TS: the gas evolved does not turn moistened red litmus paper blue.

(4) Sulfate—Dissolve 0.20 g of Morphine Hydrochloride in 5 mL of water, and add 2 to 3 drops of barium chloride TS: no turbidity is produced.

(5) Meconic acid—Dissolve 0.20 g of Morphine Hydrochloride in 5 mL of water, and add 5 mL of dilute hydrochloric acid and 2 drops of iron (III) chloride TS: no red color develops.

(6) Other alkaloids—Dissolve 0.1 g of Morphine Hydrochloride in 10 mL of diluted ethanol (95) (1 in 2), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add diluted ethanol (95) (1 in 2) 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 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethanol (99.5), toluene, acetone and ammonia solution (28) (14:14:7:1) to a distance of about 15 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 13 - 15% (0.1 g, direct titration).

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

Assay Weigh accurately about 0.5 g of Morphine Hydrochloride, dissolve in 3.0 mL of formic acid, add 100 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), mix, 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
= 32.180 mg of $C_{17}H_{19}NO_3.HCl$

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

Morphine Hydrochloride Injection

塩酸モルヒネ注射液

Morphine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 93% and not more than 107% of the labeled amount of morphine hydrochloride ($C_{17}H_{19}NO_3.HCl.3H_2O$: 375.84).

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

Description Morphine Hydrochloride Injection is a clear, colorless liquid.

It is affected by light.

pH: 2.5 - 5.0

Identification Take a volume of Morphine Hydrochloride Injection, equivalent to 0.04 g of Morphine Hydrochloride according to the labeled amount, add water to make 20 mL, and use this solution as the sample solution. To 5 mL of the sample solution add water to make 100 mL, and determine the absorption spectrum as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 283 nm and 287 nm. And to 5 mL of the sample solution add dilute sodium hydroxide TS to make 100 mL, and determine the absorption spectrum: it exhibits a maximum between 296 nm and 300 nm.

Assay Take exactly a volume of Morphine Hydrochloride Injection, equivalent to about 0.08 g of morphine hydrochloride ($C_{17}H_{19}NO_3.HCl.3H_2O$), and add water to make exactly 20 mL. Pipet 5 mL of this solution, add exactly 10 mL of the internal standard solution and water to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.025 g of morphine hydrochloride for assay, dissolve in exactly 10 mL of the internal standard solution, add water to make 50 mL, and use this solution as the standard solution. Perform the test with 20 μL 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 morphine to that of the internal standard.

Amount (mg) of morphine hydrochloride ($C_{17}H_{19}NO_3.HCl.3H_2O$)
= amount (mg) of morphine hydrochloride for assay, calculated on the anhydrous basis

$$\times 1.1680 \times \frac{Q_T}{Q_S} \times 4$$

Internal standard solution—A solution of etilefrine hydrochloride (1 in 500).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 285 nm).

Column: A stainless steel column about 4 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (about 5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 1.0 g of sodium lauryl sulfate in 500 mL of diluted phosphoric acid (1 in 1000), and adjust the pH to 3.0 with sodium hydroxide TS. To 240 mL of this solution add 70 mL of tetrahydrofuran, and mix.

Flow rate: Adjust the flow rate so that retention time of morphine is about 10 minutes.

Selection of column: Proceed with 20 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of morphine and the internal standard in this order with the resolution between these peaks being not less than 3.

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Morphine Hydrochloride Tablets

塩酸モルヒネ錠

Morphine Hydrochloride Tablets contain not less than 93% and not more than 107% of the labeled amount of morphine hydrochloride ($C_{17}H_{19}NO_3$.HCl.$3H_2O$: 375.84).

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

Identification Weigh a quantity of powdered Morphine Hydrochloride Tablets equivalent to 0.01 g of Morphine Hydrochloride, add 100 mL of water, shake for 10 minutes, and filter. Determine the absorption spectrum of the filtrate as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 283 nm and 287 nm. And weigh a quantity of powdered Morphine Hydrochloride Tablets equivalent to 0.01 g of Morphine Hydrochloride, add 100 mL of dilute sodium hydroxide TS, shake for 10 minutes, and filter. Determine the absorption spectrum of the filtrate: it exhibits a maximum between 296 nm and 300 nm.

Assay Take not less than 20 Morphine Hydrochloride Tablets, weigh accurately, and powder. Weigh accurately a quantity of the powder, equivalent to about 0.02 g of morphine hydrochloride ($C_{17}H_{19}NO_3$.HCl.$3H_2O$), add exactly 10 mL of the internal standard solution, extract the mixture with ultrasonic waves for 10 minutes, and add water to make 50 mL. Filter this solution, and use the filtrate as the sample solution. Separately, weigh accurately about 0.025 g of morphine hydrochloride for assay, dissolve in exactly 10 mL of the internal standard solution, add water to make 50 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following operating conditions, and calculate the ratios, Q_T and Q_S, of the peak area of morphine to that of the internal standard.

Amount (mg) of morphine hydrochloride ($C_{17}H_{19}NO_3$.HCl.$3H_2O$)
= amount (mg) of morphine hydrochloride for assay, calculated on the anhydrous basis
$\times 1.1680 \times \frac{Q_T}{Q_S}$

Internal standard solution—A solution of etilefrine hydrochloride (1 in 500).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 285 nm).

Column: A stainless steel column about 4 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (about 5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 1.0 g of sodium lauryl sulfate in 500 mL of diluted phosphoric acid (1 in 1000), and adjust the pH to 3.0 with sodium hydroxide TS. To 240 mL of this solution add 70 mL of tetrahydrofuran, and mix.

Flow rate: Adjust the flow rate so that the retention time of morphine is about 10 minutes.

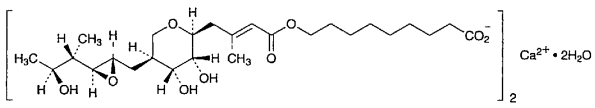
Selection of column: Proceed with 20 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of morphine and the internal standard in this order with the resolution between these peaks being not less than 3.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Mupirocin Calcium Hydrate

ムピロシンカルシウム 水和物



$C_{52}H_{86}CaO_{18}.2H_2O$: 1075.34

Monocalcium bis[9-((2*E*)-4-{(2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-epoxy-5-hydroxy-4-methylhexyl]-3,4-dihydroxy-3,4,5,6-tetrahydro-2*H*-pyran-2-yl}-3-methylbut-2-enoyloxy)nonanoate] dihydrate [*115074-43-6*]

Mupirocin Calcium Hydrate contains not less than 855 μg (potency) per mg, calculated on the anhydrous basis. The potency of Mupirocin Calcium Hydrate is expressed as mass (potency) of mupirocin ($C_{26}H_{44}O_9$: 500.62).

Description Mupirocin Calcium Hydrate occurs as a white powder and has a bitter taste.

It is freely soluble in methanol and slightly soluble in