Amount (mg) of morphine ($C_{17}H_{19}NO_3$)
= amount (mg) of morphine hydrochloride for assay, calculated on the anhydrous basis
$\times \frac{Q_T}{Q_S} \times 0.8867 \times 5$

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 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (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.

System suitability—

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, morphine and the internal standard are eluted in this order with the resolution between these peaks being not less than 3.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of morphine to that of the internal standard is not more than 1.0%.

(2) Other opium alkaloids—Weigh accurately about 1 g of Opium Alkaloids Hydrochlorides, dissolve in 20 mL of water, add 25 mL of sodium hydroxide TS, and extract successively with 50 mL, 40 mL, 30 mL and 20 mL of chloroform. Combine the chloroform extracts, and wash the extract with 10 mL of water. Filter the chloroform through a filter paper previously moistened with chloroform. Extract the washing with two 5-mL portions of chloroform, filter the chloroform extracts through the filter paper, and combine all of the filtrates. Wash the filter paper with four 5-mL portions of chloroform, and combine the washings with the combined filtrate. Evaporate the chloroform on a water bath, add 2 mL of ethanol (99.5) after the odor of chloroform is no longer perceptible, and evaporate to dryness. Dry the residue at 105°C for 4 hours, and weigh as other opium alkaloids.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Opium Alkaloids Hydrochlorides Injection

塩酸アヘンアルカロイド注射液

Opium Alkaloids Hydrochlorides Injection is an aqueous solution for injection.

It contains not less than 0.90 w/v% and not more than 1.10 w/v% of morphine ($C_{17}H_{19}NO_3$: 285.34).

Method of preparation

Opium Alkaloids Hydrochlorides	20 g
Water for Injection	a sufficient quantity
To make	1000 mL

Prepare as directed under Injections, with the above ingredients.

Description Opium Alkaloids Hydrochlorides Injection is a clear, colorless or light brown liquid.

It is affected by light.

pH: 2.5 - 3.5

Identification To 1 mL of Opium Alkaloids Hydrochlorides Injection add 1 mL of ethanol (99.5), mix, and use this solution as the sample solution, and proceed as directed in the Identification (1) under Opium Alkaloids Hydrochlorides.

Assay Pipet 2 mL of Opium Alkaloids Hydrochlorides Injection, add exactly 10 mL of the internal standard solution and water to make 50 mL, and use this solution as the sample solution. Proceed as directed in the Assay (1) under Opium Alkaloids Hydrochlorides.

Amount (mg) of morphine ($C_{17}H_{19}NO_3$)
= amount (mg) of morphine hydrochloride for assay, calculated on the anhydrous basis
$\times \frac{Q_T}{Q_S} \times 0.8867$

Internal standard solution—A solution of Etilefrine Hydrochloride (1 in 500).

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

Storage—Light-resistant.