minocycline and the spot mentioned above is not more than 2.0%.

Operating conditions—

Detector, column, column temperature, and mobile phase: Proceed as directed in the operating conditions in the Assay.

Flow rate: Adjust the flow rate so that the retention time of minocycline is about 12 minutes. The retention time of epiminocycline is about 10 minutes under this condition.

Time span of measurement: About 2.5 times as long as the retention time of minocycline after the solvent peak.

System suitability—

Test for required detection: Dissolve 0.02 g of Minocycline Hydrochloride Reference Standard in the mobile phase to make exactly 100 mL, then pipet 10 mL of this solution, and add the mobile phase to make exactly 100 mL. Adjust that the peak height of minocycline obtained from 20 μL of this solution is about 20 mm.

System performance: Proceed as directed in the system suitability in the Assay.

System repeatability: Dissolve 0.02 g of Minocycline Hydrochloride Reference Standard in the mobile phase to make exactly 100 mL, then pipet 10 mL of this solution, and add the mobile phase to make exactly 100 mL. When the test is repeated 6 times with 20 μL of this solution under the above operating conditions, the relative standard deviation of the peak areas of minocycline is not more than 2%.

Water Not less than 4.3% and not more than 8.0% (0.3 g, volumetric titration, direct titration).

Residue on ignition Not more than 0.5% (1 g).

Assay Weigh accurately an amount of Minocycline Hydrochloride and Minocycline Hydrochloride Reference Standard, equivalent to about 0.05 g (potency), dissolve each in the mobile phase to make exactly 100 mL, and use these solutions as the sample solution and the standard solution. Perform the test with exactly 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 peak areas, A_T and A_S, of minocycline of these solutions.

Amount [μg (potency)] of minocycline ($C_{23}H_{27}N_3O_7$) = amount [mg (potency)] of Minocycline Hydrochloride Reference Standard $\times \frac{A_T}{A_S} \times 1000$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 280 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 25°C.

Mobile phase: Adjust the pH of a mixture of a solution of ammonium oxalate monohydrate (7 in 250), *N,N*-dimethylformamide and 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate TS (11:5:4) to 6.2 with tetrabutylammonium hydroxide TS.

Flow rate: Adjust the flow rate so that the retention time of minocycline is about 12 minutes.

System suitability—

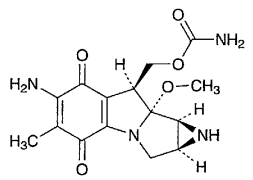
System performance: Dissolve 0.05 g (potency) of Minocycline Hydrochloride Reference Standard in 25 mL of water. Heat 5 mL of this solution on a water bath for 60 minutes, then add water to make 25 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, epiminocycline and minocycline are eluted in this order with the resolution between these peaks being not less than 2.0.

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 peak areas of minocycline is not more than 2.0%.

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

Mitomycin C

マイトマイシン C



$C_{15}H_{18}N_4O_5$: 334.33
(1a*S*,8*S*,8a*R*,8b*S*)-6-Amino-4,7-dioxo-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methylazirino[2′,3′:3,4]pyrrolo-[1,2-*a*]indol-8-ylmethyl carbamate [*50-07-7*]

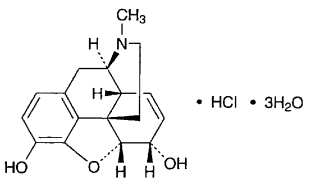
Mitomycin C conforms to the requirements of Mitomycin C in the Requirements for Antibiotic Products of Japan.

Description Mitomycin C occurs as blue-purple crystals or crystalline powder.

It is slightly soluble in water and in ethanol (95), and practically insoluble in diethyl ether.

Morphine Hydrochloride

塩酸モルヒネ



$C_{17}H_{19}NO_3.HCl.3H_2O$: 375.84
(5*R*,6*S*)-7,8-Didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol monohydrochloride trihydrate [*6055-06-7*]

Morphine Hydrochloride contains not less than 98.0% and not more than 102.0% of $C_{17}H_{19}NO_3.HCl$: 321.80, calculated on the anhydrous basis.

Description Morphine Hydrochloride occurs as white crystals or crystalline powder.