solution as the standard solution. Take exactly 0.5 mL of the standard solution, perform the test in the same manner as described for the sample solution, and determine the absorbances, A_{S2} and A_{S6}, of the solution after having allowed it to stand for exactly 2 and 6 minutes. Separately, take exactly 1 mL of trypsin in-hibitor TS, and add 0.05 mol/L phosphate buffer solution, pH 7.0 to make exactly 10 mL. Pipet 0.5 mL of this solution, perform the test in the same manner as described for the sample solution, and determine the absorbances, A_{02} and A_{06}, of the solution after having allowed it to stand for exactly 2 and 6 minutes.

$$\text{Units per 1 mg of Kallidinogenase} = \frac{(A_{T6} - A_{T2}) - (A_{06} - A_{02})}{(A_{S6} - A_{S2}) - (A_{06} - A_{02})} \times \frac{a}{10} \times \frac{1}{b}$$

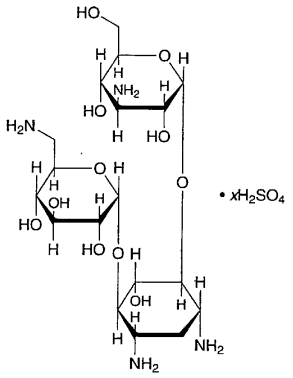
a: Amount (Units) of Kallidinogenase Reference Standard sampled.

b: Amount (mg) of Kallidinogenase in 1 mL of the sample stock solution.

Cantainers and storage Containers—Tight containers.

Kanamycin Sulfate

硫酸カナマイシン



$C_{18}H_{36}N_4O_{11}.xH_2SO_4$

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→6)-*O*-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→4)]-2-deoxy-D-streptamine sulfate [*133-92-6*]

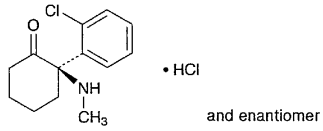
Kanamycin Sulfate conforms to the requirements of Kanamycin Sulfate in the Requirements for Antibiotic Products of Japan.

Description Kanamycin Sulfate occurs as a white to yellowish white powder.

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

Ketamine Hydrochloride

塩酸ケタミン



$C_{13}H_{16}ClNO.HCl$: 274.19

(*RS*)-2-(2-Chlorophenyl)-2-methylaminocyclohexanone monohydrochloride [*1867-66-9*]

Ketamine Hydrochloride, when dried, contains not less than 99.0% of $C_{13}H_{16}ClNO.HCl$.

Description Ketamine Hydrochloride occurs as white crystals or crystalline powder.

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

A solution of Ketamine Hydrochloride (1 in 10) shows no optical rotation.

Melting point: about 258°C (with decomposition).

Identification (1) Determine the absorption spectrum of a solution of Ketamine Hydrochloride in 0.1 mol/L hydrochloric acid TS (1 in 3000) 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.

(2) Determine the infrared absorption spectrum of Ketamine Hydrochloride, previously dried, 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 Ketamine Hydrochloride (1 in 10) responds to the Qualitative Tests (2) for chloride.

Absorbance $E^{1\%}_{1\,cm}$ (269 nm): 22.0 – 24.5 (after drying, 0.03 g, 0.1 mol/L hydrochloric acid TS, 100 mL).

pH Dissolve 1.0 g of Ketamine Hydrochloride in 10 mL of freshly boiled and cooled water: the pH of the solution is between 3.5 and 4.5.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Ketamine Hydrochloride in 5 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Ketamine Hydrochloride according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

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

(4) Related substances—Dissolve 0.5 g of Ketamine Hydrochloride in 10 mL of methanol and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol 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 2 μL 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 cyclohexane and isopropylamine (49:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly Dragendorff's TS for spraying on the plate, dry the plate, and then spray evenly hydrogen peroxide TS: the spots other than the principal spot from the sample solution is not more intense than the spot from the standard solution.

Loss on drying Not more then 0.5% (1 g, 105°C, 3 hours).

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

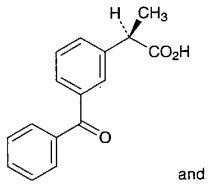
Assay Weigh accurately about 0.5 g of Ketamine Hydrochloride, previously dried, dissolve in 1 mL of formic acid, add 70 mL of a mixture of acetic anhydride and acetic acid (100) (6:1), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 27.149 mg of $C_{13}H_{16}ClNO.HCl$

Containers and storage Containers—Tight containers.

Ketoprofen

ケトプロフェン



and enantiomer

$C_{16}H_{14}O_3$: 254.28
(*RS*)-2-(3-Benzoylphenyl)propanoic acid [*22071-15-4*]

Ketoprofen, when dried, contains not less than 98.5% of $C_{16}H_{14}O_3$.

Description Ketoprofen occurs as a white, crystalline powder.

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

It is colored by light.

Identification **(1)** Dissolve 0.01 g of Ketoprofen in 1 mL of methanol, add 2 mL of 2,4-dinitrophenylhydrazine TS, and allow to stand for 30 minutes: an orange-yellow precipitate is formed.

(2) Determine the absorption spectrum of a solution of Ketoprofen in methanol (1 in 200,000) 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.

(3) Determine the infrared absorption spectrum of Ketoprofen, previously dried, 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.

Melting point 94 - 97°C

Purity **(1)** Clarity and color of solution—Dissolve 0.5 g of Ketoprofen in 10 mL of methanol: the solution is clear and colorless.

(2) Chloride—Dissolve 2.0 g of Ketoprofen in 40 mL of methanol, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.30 mL of 0.01 mol/L hydrochloric acid VS add 40 mL of methanol, 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.005%).

(3) Sulfate—Dissolve 2.0 g of Ketoprofen in 40 mL of methanol, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.40 mL of 0.005 mol/L sulfuric acid VS add 40 mL of methanol, 1 mL of dilute hydrochloric acid and water to make 50 mL (not more than 0.010%).

(4) Heavy metals—Proceed with 2.0 g of Ketoprofen according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of Ketoprofen according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(6) Related substances—Conduct this procedure with a minimum of exposure to light, using light-resistant vessels. Dissolve 0.10 g of Ketoprofen in 10 mL of methanol, and use this solution as the sample solution. Pipet 2 mL of the sample solution, and add methanol to make exactly 100 mL. Pipet 5 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 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 carbon tetrachloride and acetic acid (100) (9:1) 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.

Loss on drying Not more than 0.5% (0.5 g, in vacuum, 60°C, 24 hours).

Residue on ignition Not more than 0.14% (1 g).

Assay Weigh accurately about 0.3 g of Ketoprofen, previously dried, dissolve in 25 mL of ethanol (95), add 25 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 25.429 mg of $C_{16}H_{14}O_3$

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