

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 inhibitor 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.

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

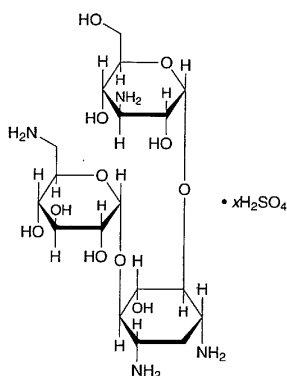
a: Amount (Units) of Kallidinogenase Reference Standard sampled.

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

Containers and storage Containers—Tight containers.

Kanamycin Sulfate

硫酸カナマイシン



$C_{18}H_{36}N_4O_{11} \cdot xH_2SO_4$
O-3-Amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)-*O*-[6-amino-6-deoxy- α -D-glucopyranosyl-(1 \rightarrow 4)]-2-deoxy-D-streptamine sulfate [133-92-6]

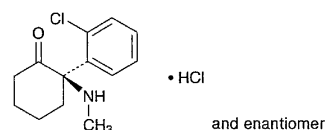
Kanamycin Sulfate conforms to the requirements of Kanamycin Sulfate in the Requirements for Antibiotic Products of Japan.

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



$C_{13}H_{16}ClNO \cdot HCl$: 274.19
(RS)-2-(2-Chlorophenyl)-2-methylaminocyclohexanone monohydrochloride [1867-66-9]

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

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 $E_{1\text{cm}}^{1\%}$ (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.