

3 hours, and determine the melting point.

**Purity (1)** Clarity and color of solution—Dissolve 1.0 g of Acetylcholine Chloride for Injection in 10 mL of water: the solution is clear and colorless.

(2) Acid—Dissolve 0.10 g of Acetylcholine Chloride for Injection in 10 mL of freshly boiled and cooled water, and add 1 drop of bromothymol blue TS, and 0.30 mL of 0.01 mol/L sodium hydroxide VS: the solution is blue in color.

(3) Heavy metals—Proceed with 2.0 g of Acetylcholine Chloride for Injection according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

**Loss on drying** Not more than 1.0% (1 g, 105°C, 3 hours).

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

**Assay (1)** Acetylcholine chloride—Weigh accurately the contents of not less than 10 Acetylcholine Chloride for Injections. Weigh accurately about 0.5 g of the contents, dissolve in 15 mL of water, then add exactly 40 mL of 0.1 mol/L sodium hydroxide VS, stopper loosely, and heat on a water bath for 30 minutes. Cool quickly, and titrate the excess sodium hydroxide with 0.05 mol/L sulfuric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS  
= 18.166 mg of  $C_7H_{16}ClNO_2$

(2) Chlorine—Titrate the solution, which has been titrated in (1), with 0.1 mol/L silver nitrate VS (indicator: 3 drops of fluorescein sodium TS).

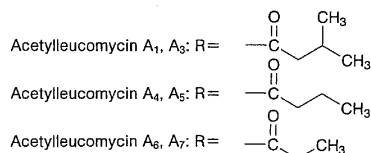
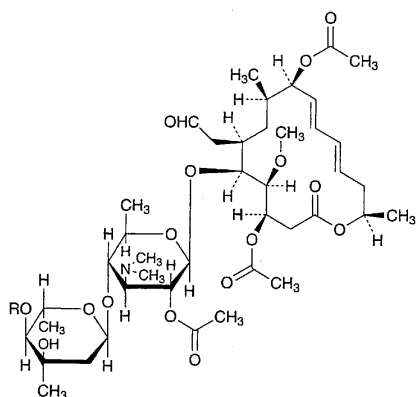
Each mL of 0.1 mol/L silver nitrate VS  
= 3.5453 mg of Cl

**Containers and storage** Containers—Hermetic containers.

## Acetylkitasamycin

### Acetylleucomycin

アセチルキタサマイシン



(3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-3,9-Diacetoxy-5-[O-(4-*O*-acyl-2,6-dideoxy-3-*C*-methyl- $\alpha$ -*L*-ribo-hexopyranosyl)-(1→4)-2-*O*-acetyl-3,6-dideoxy-3-dimethylamino- $\beta$ -D-glucopyranosyloxy]-6-formylmethyl-4-methoxy-8-methyl-hexadeca-10,12-dien-15-olide

Acetylleucomycins A<sub>1</sub>, A<sub>3</sub>: acyl = 3-methylbutanoyl

Acetylleucomycins A<sub>4</sub>, A<sub>5</sub>: acyl = butanoyl

Acetylleucomycins A<sub>6</sub>, A<sub>7</sub>: acyl = propanoyl

Acetylkitasamycin contains not less than 560  $\mu$ g (potency) per mg, calculated on the anhydrous basis. The potency of Acetylkitasamycin is expressed as mass (potency) of kitasamycin corresponding to the mass of leucomycin A<sub>5</sub> ( $C_{39}H_{65}NO_{14}$ : 771.94). One mg (potency) of kitasamycin is equivalent to 0.530 mg of leucomycin A<sub>5</sub> ( $C_{39}H_{65}NO_{14}$ ).

**Description** Acetylkitasamycin occurs as a white to light yellow-white powder.

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

**Identification (1)** Determine the absorption spectrum of a solution of Acetylkitasamycin in methanol (1 in 40,000) 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 wavelength.

(2) Determine the infrared absorption spectrum of Acetylkitasamycin 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.

**Water** Not more than 5.0% (0.1 g, volumetric titration, direct titration).

**Assay** Perform the test according to the Cylinder-plate method as directed under the Microbial Assay for Antibiotics according to the following conditions.

(1) Test organism—*Bacillus subtilis* ATCC 6633

(2) Culture medium—Use the medium i in 1) Medium for test organism [5] under (1) Agar media for seed and base layer.

(3) Standard solution—Weigh accurately an amount of Kitasamycin Reference Standard equivalent to about 0.03 g (potency), dissolve in 10 mL of methanol, add water to make exactly 100 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 3 days. Take exactly a suitable amount of the standard stock solution before use, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 30  $\mu$ g (potency) and 7.5  $\mu$ g (potency), and use these solutions as the high concentration standard solution and the low concentration standard solution, respectively.

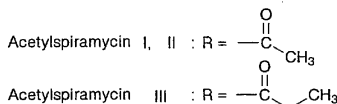
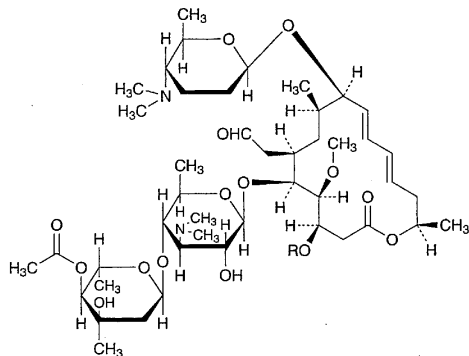
(4) Sample solution—Weigh accurately an amount of Acetylkitasamycin equivalent to about 0.03 g (potency), dissolve in 25 mL of methanol, add water to make exactly 50 mL, shake well, and allow to stand at 37  $\pm$  2°C for 24 hours. Take exactly a suitable amount of the solution, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 30  $\mu$ g (potency) and 7.5  $\mu$ g (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution,

respectively.

**Containers and storage** Containers—Tight containers.

## Acetylspiramycin

アセチルスピラマイシン



(Acetylspiramycins I, II)  
 (3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-3-Acetoxy-5-[*O*-(4-*O*-acetyl-2,6-dideoxy-3-*C*-methyl- $\alpha$ -*L*-ribo-hexopyranosyl)-(1 $\rightarrow$ 4)-3,6-dideoxy-3-dimethylamino- $\beta$ -*D*-glucopyranosyloxy]-9-(2,3,4,6-tetraoexo-4-dimethylamino- $\beta$ -*D*-erythro-hexopyranosyloxy)-6-formylmethyl-9-hydroxy-4-methoxy-8-methylhexadeca-10,12-dien-15-olide

(Acetylspiramycin III)  
 (3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-5-[*O*-(4-*O*-Acetyl-2,6-dideoxy-3-*C*-methyl- $\alpha$ -*L*-ribo-hexopyranosyl)-(1 $\rightarrow$ 4)-3,6-dideoxy-3-dimethylamino- $\beta$ -*D*-glucopyranosyloxy]-9-(2,3,4,6-tetraoexo-4-dimethylamino- $\beta$ -*D*-erythro-hexopyranosyloxy)-6-formylmethyl-9-hydroxy-4-methoxy-8-methyl-3-propionyloxyhexadeca-10,12-dien-15-olide [74014-51-0, Acetylspiramycin]

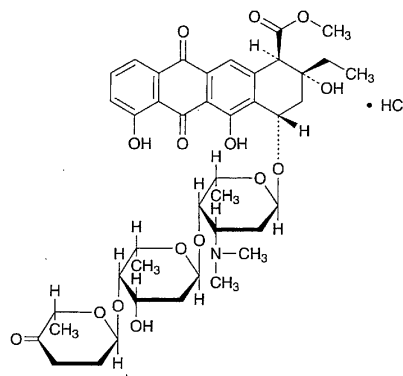
Acetylspiramycin conforms to the requirements of Acetylspiramycin in the Requirements for Antibiotic Products of Japan.

**Description** Acetylspiramycin occurs as a white to light yellowish white powder. It has a bitter taste.

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

## Aclarubicin Hydrochloride

塩酸アクラルビシン



$\text{C}_{42}\text{H}_{53}\text{NO}_{15} \cdot \text{HCl}$ : 848.33

Methyl (1*R*,2*R*,4*S*)-4-[*O*-(2,6-dideoxy-4-*O*-[(2*R*,6*S*)-tetrahydro-6-methyl-5-oxopyran-2-yl]- $\alpha$ -*L*-lyxo-hexopyranosyl)-(1 $\rightarrow$ 4)-2,3,6-trideoxy-3-dimethylamino-*L*-lyxo-hexopyranosyloxy)-2-ethyl-1,2,3,4,6,11-hexahydro-2,5,7-trihydroxy-6,11-dioxonaphthacene-1-carboxylate monohydrochloride [75443-99-1]

Aclarubicin Hydrochloride conforms to the requirements of Aclarubicin Hydrochloride in the Requirements for Antibiotic Products of Japan.

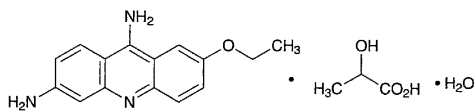
**Description** Aclarubicin Hydrochloride occurs as a yellow to pale orange-yellow powder.

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

## Acrinol

### Ethacridine Lactate

アクリノール



$\text{C}_{15}\text{H}_{15}\text{N}_3\text{O} \cdot \text{C}_3\text{H}_6\text{O}_3 \cdot \text{H}_2\text{O}$ : 361.39

2-Ethoxy-6,9-diaminoacridine monolactate monohydrate [1837-57-6]

Acrinol contains not less than 99.0% of  $\text{C}_{15}\text{H}_{15}\text{NO} \cdot \text{C}_3\text{H}_6\text{O}_3 \cdot \text{H}_2\text{O}$ .

**Description** Acrinol occurs as a yellow, crystalline powder. It is odorless, and has an astringent, bitter taste.

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

A solution of Acrinol (1 in 100) is neutral.

Melting point: about 245°C (with decomposition).