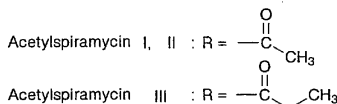
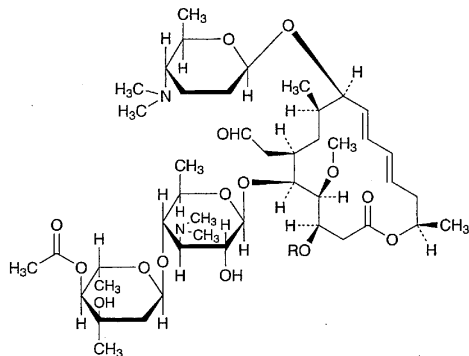


respectively.

**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]

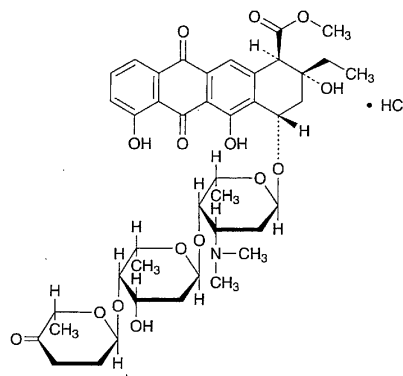
Acetylspiramycin conforms to the requirements of Acetylspiramycin in the Requirements for Antibiotic Products of Japan.

**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.

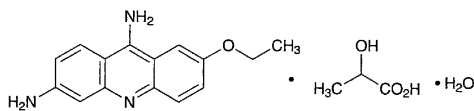
**Description** Aclarubicin Hydrochloride occurs as a yellow to pale orange-yellow powder.

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).

**Identification (1)** A solution of Acrinol (1 in 40,000) shows a green fluorescence.

(2) To 5 mL of a solution of Acrinol (1 in 100) add 2 drops each of sodium nitrite TS and dilute hydrochloric acid: a dark red color is produced.

(3) To 5 mL of a solution of Acrinol (1 in 1000) add 3 drops of iodine TS: a deep, blue-green precipitate is formed, which dissolves on the addition of ethanol (95).

(4) To 5 mL of a solution of Acrinol (1 in 100) add 5 mL of dilute sulfuric acid, shake well, allow to stand for about 10 minutes at room temperature, and filter: the filtrate responds to the Qualitative Tests for lactate.

**Purity (1) Chloride**—Dissolve 1.0 g of Acrinol in 80 mL of water by warming on a water bath, cool, and add 10 mL of sodium hydroxide TS and water to make 100 mL. Shake well, allow to stand for 30 minutes, filter, to 40 mL of the filtrate add 7 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare 50 mL of the control solution with 4 mL of sodium hydroxide TS, 7 mL of dilute nitric acid, 0.30 mL of 0.01 mol/L hydrochloric acid VS and water (not more than 0.026%).

(2) **Sulfate**—Dissolve 0.5 g of Acrinol in 20 mL of water by heating, cool, add 2 mL of dilute hydrochloric acid, shake well, allow to stand for 30 minutes, filter, and to the filtrate add 3 drops of barium chloride TS: no turbidity is produced.

(3) **Ammonium**—Dissolve 0.5 g of Acrinol in 20 mL of water by heating, after cooling, add 0.5 mL of sodium hydroxide TS, filter, and boil the filtrate: the gas evolved does not change moistened red litmus paper to blue.

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

(5) **Volatile fatty acids**—Dissolve 0.5 g of Acrinol in a mixture of 20 mL of water and 5 mL of dilute sulfuric acid, shake well, filter, and heat the filtrate: no odor of volatile fatty acids is perceptible.

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

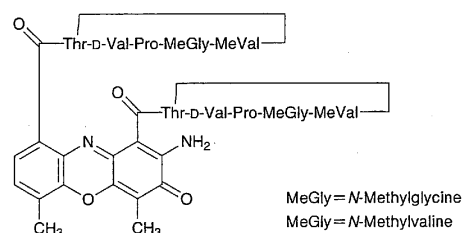
**Assay** Weigh accurately about 0.3 g of Acrinol, place in a 100-mL volumetric flask, add 25 mL of water, 20 mL of sodium acetate TS and 1.25 mL of dilute hydrochloric acid, and dissolve. Add exactly 50 mL of 1/60 mol/L potassium dichromate VS and water to make exactly 100 mL. Allow to stand for 1 hour with frequent shaking, and filter. Discard the first 20 mL of the filtrate, pipet the next 50 mL into an iodine-flask, and add 30 mL of dilute sulfuric acid and 6 mL of potassium iodide TS. Immediately stopper closely, and allow to stand for 5 minutes in a dark place. Add 50 mL of water, and titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS). Perform a blank determination.

Each mL of 1/60 mol/L potassium dichromate VS  
= 12.047 mg of  $C_{15}H_{15}N_3O \cdot C_3H_6O_3 \cdot H_2O$

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

## Actinomycin D

アクチノマイシン D



$C_{62}H_{86}N_{12}O_{16}$ : 1255.42

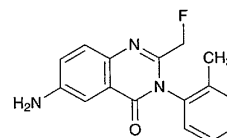
Actinomycin D conforms to the requirements of Actinomycin D in the Requirements for Antibiotic Products of Japan.

**Description** Actinomycin D occurs as an orange-red to red, crystalline powder.

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

## Afloqualone

アフロクアロン



$C_{16}H_{14}FN_3O$ : 283.30

6-Amino-2-fluoromethyl-3-(2-tolyl)-3H-quinazolin-4-one  
[56287-74-2]

Afloqualone, when dried, contains not less than 98.5% of  $C_{16}H_{14}FN_3O$ .

**Description** Afloqualone occurs as white to light yellow crystals or crystalline powder.

It is soluble in acetonitrile, sparingly soluble in ethanol (99.5), and practically insoluble in water.

It is gradually colored by light.

Melting point: about 197°C (with decomposition).

**Identification (1)** Conduct this procedure without exposure to light, using light-resistant containers. Determine the absorption spectrum of a solution of Afloqualone in ethanol (99.5) (1 in 150,000) 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 Afloqualone, 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.