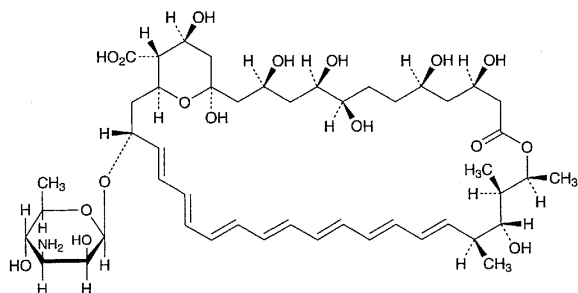


**Containers and storage** Containers—Tight containers.

## Amphotericin B

アムホテリシン B



$C_{47}H_{73}NO_{17}$ : 924.08  
(1*R*,3*S*,5*R*,6*R*,9*R*, 11*R*, 15*S*, 16*R*, 17*R*, 18*S*, 19*E*, 21*E*, 23*E*,25*E*,27*E*,29*E*,31*E*,33*R*,35*S*,36*S*,37*S*)-33-(3-Amino-3,6-dideoxy- $\beta$ -D-mannopyranosyloxy)-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid [1397-89-3]

Amphotericin B contains not less than 840  $\mu$ g (potency) per mg, calculated on the dried basis. The potency of Amphotericin B is expressed as mass (potency) of amphotericin B ( $C_{47}H_{73}NO_{17}$ ).

**Description** Amphotericin B occurs as a yellow to orange powder.

It is freely soluble in dimethylsulfoxide and practically insoluble in water and in ethanol (95).

**Identification** (1) Dissolve 5 mg of Amphotericin B in 10 mL of dimethylsulfoxide. To 1 mL of this solution add 5 mL of phosphoric acid: a blue color develops between the two layers, and the solution becomes blue by shaking. After addition of 15 mL of water it becomes yellow to light yellow-brown by shaking.

(2) Dissolve 0.025 g of Amphotericin B in 5 mL of dimethylsulfoxide, and add methanol to make 50 mL. To 1 mL of this solution add methanol to make 50 mL. Determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Amphotericin B Reference Standard: both spectra exhibit similar intensities of absorption at the same wavelength.

**Purity** Amphotericin A—Weigh accurately about 0.05 g each of Amphotericin B and Amphotericin B Reference Standard, add exactly 10 mL each of dimethylsulfoxide to dissolve, and add methanol to make exactly 50 mL. Pipet 4 mL each of these solutions, add methanol to make exactly 50 mL, and use these solutions as the sample solution and the standard solution (1), respectively. Separately, weigh accurately about 0.02 g of Nystatin Reference Standard, add exactly 40 mL of dimethylsulfoxide to dissolve, then add methanol to make exactly 200 mL. Pipet 4 mL of this solution, add methanol to make exactly 50 mL, and use this solu-

tion as the standard solution (2). Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry using a solution obtained in the same manner as the sample solution as the blank, and determine the absorbances at 282 nm and at 304 nm. Calculate the amount of amphotericin A by the following equation: not more than 5% for Amphotericin B used for injections, and not more than 15% for Amphotericin B not used for injections.

$$\begin{aligned} & \text{Amount (\% of amphotericin A)} \\ &= \left[ \frac{\text{amount (mg) of Nystatin Reference Standard}}{\text{amount (mg) of the sample}} \right] \\ & \times \frac{[A_{Sa1} \times A_{T2}] - (A_{Sa2} \times A_{T1})}{[(A_{Sa1} \times A_{Sb2}) - (A_{Sa2} \times A_{Sb1})]} \times 25 \end{aligned}$$

$A_{Sb1}$ : Absorbance at 282 nm of the standard solution (2)

$A_{Sa1}$ : Absorbance at 282 nm of the standard solution (1)

$A_{Sb2}$ : Absorbance at 304 nm of the standard solution (2)

$A_{Sa2}$ : Absorbance at 304 nm of the standard solution (1)

$A_{T1}$ : Absorbance at 282 nm of the sample solution

$A_{T2}$ : Absorbance at 304 nm of the sample solution

**Loss on drying** Not more than 5.0% (0.1 g, in vacuum, 60°C, 3 hours).

**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—*Saccharomyces cerevisiae* ATCC 9763

(2) Culture medium—Use the medium 2) Medium for test organism [12] under (1) Agar media for seed and base layer.

(3) Preparation of cylinder-agar plate—Proceed as directed in 5 under the Cylinder plate method, using Petri dish plates not dispensing the agar medium for base layer and dispensing 8.0 mL of the seeded agar medium.

(4) Standard solution—Use light-resistant vessels. Weigh accurately an amount of Amphotericin B Reference Standard equivalent to about 0.02 g (potency), dissolve in dimethylsulfoxide to make exactly 20 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 24 hours. Take exactly a suitable amount of the standard stock solution before use, and add dimethylsulfoxide to make solutions so that each mL contains 200  $\mu$ g (potency) and 50  $\mu$ g (potency). Pipet 1 mL each of these solutions, add 0.2 mol/L phosphate buffer solution, pH 10.5 to make exactly 20 mL, and use these solutions as the high concentration standard solution and the low concentration standard solution, respectively.

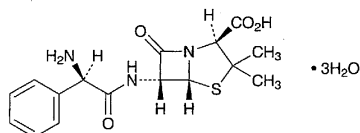
(5) Sample solution—Use light-resistant vessels. Weigh accurately an amount of Amphotericin B equivalent to about 0.02 g (potency), dissolve in dimethylsulfoxide to make exactly 20 mL, and use this solution as the sample stock solution. Take exactly a suitable amount of the sample stock solution, add dimethylsulfoxide to make solutions so that each mL contains 200  $\mu$ g (potency) and 50  $\mu$ g (potency). Pipet 1 mL each of these solutions, add 0.2 mol/L phosphate buffer solution, pH 10.5 to make exactly 20 mL, and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

**Containers and storage** Containers—Tight containers.  
Storage—Light-resistant, and in a cold place.

## Ampicillin

### Aminobenzylpenicillin

アンピシリン



$C_{16}H_{19}N_3O_4S \cdot 3H_2O$ : 403.45  
(2*S*,5*R*,6*R*)-6-[(2*R*)-2-Amino-2-phenylacetyl-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate [7177-48-2]

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

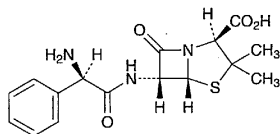
**Description** Ampicillin occurs as white to light yellowish white crystals or crystalline powder.

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

## Anhydrous Ampicillin

### Anhydrous Aminobenzylpenicillin

無水アンピシリン



$C_{16}H_{19}N_3O_4S$ : 349.40  
(2*S*,5*R*,6*R*)-6-[(2*R*)-2-Amino-2-phenylacetyl-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid [69-53-4]

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

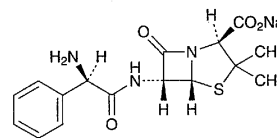
**Description** Anhydrous Ampicillin occurs as a white to light yellowish white powder.

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

## Ampicillin Sodium

### Aminobenzylpenicillin Sodium

アンピシリンナトリウム



$C_{16}H_{18}N_3NaO_4S$ : 371.39  
Monosodium (2*S*,5*R*,6*R*)-6-[(2*R*)-2-amino-2-phenylacetyl-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate [69-52-3]

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

**Description** Ampicillin Sodium occurs as white to light yellowish white crystals or crystalline powder.

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

## Amyl Nitrite

亜硝酸アミル

$C_5H_{11}NO_2$ : 117.15

Amyl Nitrite is the nitrous acid ester of 3-methylbutanol-1 and contains a small quantity of 2-methylbutanol-1 and the nitrous acid esters of other homologues.

Amyl Nitrite contains not less than 90.0% of  $C_5H_{11}NO_2$ .

**Description** Amyl Nitrite is a clear, light yellowish liquid, and has a characteristic, fruity odor.

It is miscible with ethanol (95), and with diethyl ether.

It is practically insoluble in water.

It is affected by light and by heat.

It is volatile at ordinary temperature and flammable even at a low temperature.

Boiling point: about 97°C

**Identification** Determine the infrared spectrum of Amyl Nitrite as directed in the liquid film 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.

**Specific gravity**  $d_{20}^{20}$ : 0.871 – 0.880

**Purity** (1) Acid—To 5 mL of Amyl Nitrite add a mixture of 1.0 mL of 1 mol/L sodium hydroxide VS, 10 mL of water and 1 drop of phenolphthalein TS, shake, and allow to stand for 1 minute: the light red color of the water layer does not disappear.

(2) Water—Allow 2.0 mL of Amyl Nitrite to stand in ice water: no turbidity is produced.