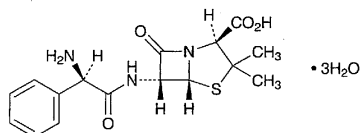


Containers and storage Containers—Tight containers.
Storage—Light-resistant, and in a cold place.

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.

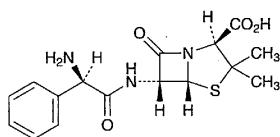
Description Ampicillin occurs as white to light yellowish white crystals or crystalline powder.

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.

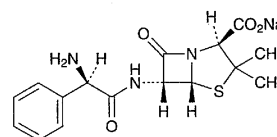
Description Anhydrous Ampicillin occurs as a white to light yellowish white powder.

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.

(3) Aldehyde—To 3 mL of a mixture of equal volumes of silver nitrate TS and aldehyde free-ethanol add ammonia TS dropwise until the precipitate first formed is redissolved. Add 1.0 mL of Amyl Nitrite, and warm between 60°C and 70°C for 1 minute: a brown to black color is not produced.

(4) Residue on evaporation—Evaporate 10.0 mL of Amyl Nitrite on a water bath in a draft, carefully protecting from flame, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Assay Weigh accurately a volumetric flask containing 10 mL of ethanol (95), add about 0.5 g of Amyl Nitrite, and weigh accurately again. Add exactly 25 mL of 0.1 mol/L silver nitrate VS, then add 15 mL of potassium chlorate solution (1 in 20) and 10 mL of dilute nitric acid, stopper the flask immediately, and shake it vigorously for 5 minutes. Dilute with water to make exactly 100 mL, shake, and filter through dry filter paper. Discard the first 20 mL of the filtrate, measure exactly 50 mL of the subsequent filtrate, and titrate the excess silver nitrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS). Perform a blank determination.

$$\begin{aligned} \text{Each mL of 0.1 mol/L silver nitrate VS} \\ = 35.144 \text{ mg of } C_5H_{11}NO_2 \end{aligned}$$

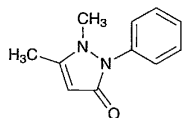
Containers and storage Containers—Hermetic containers not exceeding 10-ml capacity.

Storage—Light-resistant, in a cold place, and remote from fire.

Antipyrine

Phenazone

アンチピリン



$C_{11}H_{12}N_2O$: 188.23
1,5-Dimethyl-2-phenyl-1,2-dihydropyrazol-3-one
[60-80-0]

Antipyrine, when dried, contains not less than 99.0% of $C_{11}H_{12}N_2O$.

Description Antipyrine occurs as colorless or white crystals, or a white, crystalline powder. It is odorless, and has a slightly bitter taste.

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

A solution of Antipyrine (1 in 10) is neutral.

Identification (1) To 5 mL of a solution of Antipyrine (1 in 100) add 2 drops of sodium nitrite TS and 1 mL of dilute sulfuric acid: a deep green color develops.

(2) To 2 mL of a solution of Antipyrine (1 in 100) add 4 drops of dilute iron (III) chloride TS: a yellow-red color develops. Then add 10 drops of dilute sulfuric acid: the color changes to light yellow.

(3) To 5 mL of a solution of Antipyrine (1 in 100) add 2 to 3 drops of tannic acid TS: a white precipitate is produced.

(4) To 0.1 g of Antipyrine add 0.1 g of vanillin, 5 mL of water and 2 mL of sulfuric acid, boil the mixture, and cool: a yellow-red precipitate is produced.

Melting point 111 – 113°C

Purity (1) Chloride—Perform the test with 1.0 g of Antipyrine. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.014%).

(2) Heavy metals—Proceed with 1.0 g of Antipyrine 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) Readily carbonizable substances—Perform the test with 0.5 g of Antipyrine: the solution remains colorless.

Loss on drying Not more than 0.5% (1 g, silica gel, 4 hours).

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

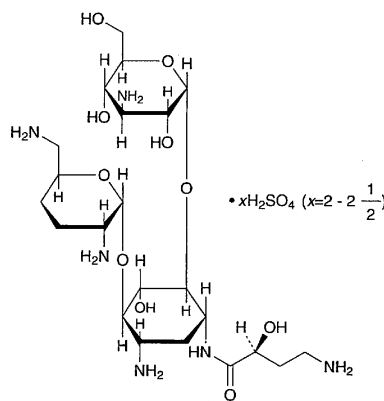
Assay Dissolve about 0.2 g of Antipyrine, previously dried and accurately weighed, in 20 mL of sodium acetate TS, add exactly 30 mL of 0.05 mol/L iodine VS, and allow to stand for 20 minutes with occasional shaking. Dissolve the precipitate in 10 mL of chloroform, and titrate the excess iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS). Perform a blank determination.

$$\begin{aligned} \text{Each mL of 0.05 mol/L iodine VS} \\ = 9.411 \text{ mg of } C_{11}H_{12}N_2O \end{aligned}$$

Containers and storage Containers—Well-closed containers.

Arbekacin Sulfate

硫酸アルベカシン



$C_{22}H_{44}N_6O_{10} \cdot xH_2SO_4$ ($x = 2 - 2\frac{1}{2}$)
O-3-Amino-3-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6)-O-[2,6-diamino-2,3,4,6-tetra-deoxy- α -D-erythro-hexopyranosyl-(1 \rightarrow 4)]-1-N-[(2S)-4-amino-2-hydroxybutanoyl]-2-deoxy-D-streptomine sulfate [51025-85-5, Arbekacin]

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