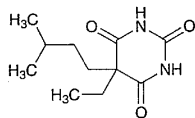


Amobarbital

アモバルビタール

C₁₁H₁₈N₂O₃: 226.275-Ethyl-5-isopentylpyrimidine-2,4,6(1*H*,3*H*,5*H*)-trione
[57-43-2]

Amobarbital, when dried, contains not less than 99.0% of C₁₁H₁₈N₂O₃.

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

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

It dissolves in sodium hydroxide TS and in sodium carbonate TS.

The pH of a saturated solution of Amobarbital is between 5.0 and 5.6.

Identification (1) Boil 0.2 g of Amobarbital with 10 mL of sodium hydroxide TS: the gas evolved changes moistened red litmus paper to blue.

(2) Dissolve 0.05 g of Amobarbital in 2 to 3 drops of ammonia-ammonium chloride buffer solution, pH 10.7, and 5 mL of diluted pyridine (1 in 10). Add 5 mL of chloroform and 0.3 mL of copper (II) sulfate TS to the solution: a red-purple precipitate is produced in the aqueous layer. Shake the mixture: a red-purple color is produced in the chloroform layer.

(3) To 0.4 g of Amobarbital add 0.1 g of anhydrous sodium carbonate and 4 mL of water, shake, and add a solution of 0.3 g of 4-nitrobenzyl chloride in 7 mL of ethanol (95). Heat the mixture on a water bath for 30 minutes under a reflux condenser, and allow to stand for 1 hour. Filter the crystals produced, wash with 7 mL of sodium hydroxide TS and a small portion of water, recrystallize from ethanol, and dry at 105°C for 30 minutes: the crystals so obtained melt between 168°C and 173°C or between 150°C and 154°C.

Melting point 157 – 160°C

Purity (1) Clarity and color of solution—Dissolve 0.5 g of Amobarbital in 5 mL of sodium hydroxide TS: the solution is clear and colorless.

(2) Chloride—Dissolve 0.30 g of Amobarbital in 20 mL of acetone, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: take 0.30 mL of 0.01 mol/L hydrochloric acid VS, 20 mL of acetone and 6 mL of dilute nitric acid, and add water to make 50 mL (not more than 0.035%).

(3) Sulfate—Dissolve 0.40 g of Amobarbital in 20 mL of acetone, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: take 0.40 mL of 0.005 mol/L sulfuric acid VS, 20 mL of ace-

tone, and 1 mL of dilute hydrochloric acid, and add water to make 50 mL (not more than 0.048%).

(4) Heavy metals—Proceed with 1.0 g of Amobarbital 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) Readily carbonizable substances—Perform the test with 0.5 g of Amobarbital. The solution has no more color than Matching Fluid A.

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

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

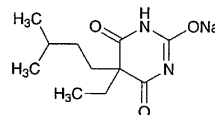
Assay Weigh accurately about 0.5 g of Amobarbital, previously dried, and dissolve in 5 mL of ethanol (95) and 50 mL of chloroform. Titrate with 0.1 mol/L potassium hydroxide-ethanol VS until the color of the solution changes from yellow through light blue to purple (indicator: 1 mL of alizarin yellow GG-thymolphthalein TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L potassium hydroxide-ethanol VS = 22.628 mg of C₁₁H₁₈N₂O₃

Containers and storage Containers—Well-closed containers.

Amobarbital Sodium for Injection

注射用アモバルビタールナトリウム

C₁₁H₁₇N₂NaO₃: 248.25

Monosodium 5-ethyl-5-isopentyl-1,4,5,6-tetrahydro-4,6-dioxypyrimidin-2-olate [64-43-7]

Amobarbital Sodium for Injection is a preparation for injection which is dissolved before use. When dried, it contains not less than 98.5% of amobarbital sodium (C₁₁H₁₇N₂NaO₃), and not less than 92.5% and not more than 107.5% of the labeled amount of amobarbital sodium (C₁₁H₁₇N₂NaO₃).

Method of preparation Prepare as directed under Injections.

Description Amobarbital Sodium for Injection occurs as white crystals or a crystalline powder. It is odorless, and has a bitter taste.

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

The pH of its solution (1 in 10) is between 10.0 and 11.0. It is hygroscopic.

Identification (1) Dissolve 1.5 g of Amobarbital Sodium for Injection in 20 mL of water, and add 10 mL of dilute hydrochloric acid with stirring: a white precipitate is produced. Collect the precipitate, wash with four 10-mL portions of water, and dry at 105°C for 3 hours: it melts be-