Pipet 1 mL of this solution, add methanol to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot  $10 \,\mu\text{L}$  each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform and methanol (9:1) to a distance of about 10 cm, and air-dry the plate. Examine the plate under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.3 g of Ethionamide, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from orange-red to dark orange-brown (indicator: 2 mL of p-naphtholbenzein TS). Perform a blank determination.

Each mL of 0.1 mol/L perchloric acid VS = 16.625 mg of  $C_8H_{10}N_2S$ 

**Containers and storage** Containers—Well-closed containers.

Storage—Light-resistant.

## **Ethosuximide**

エトスクシミド

C<sub>7</sub>H<sub>11</sub>NO<sub>2</sub>: 141.17

(RS)-2-Ethyl-2-methylsuccinimide [77-67-8]

Ethosuximide contains not less than 98.5% of  $C_7H_{11}NO_2$  calculated on the anhydrous basis.

**Description** Ethosuximide occurs as a white, paraffin-like solid or powder. It is odorless or has a slight, characteristic odor.

It is very soluble in methanol, in ethanol (95), in diethyl ether, and in *N*,*N*-dimethylformamide, and freely soluble in water.

Melting point: about 48°C

**Identification** (1) To 0.2 g of Ethosuximide add 10 mL of sodium hydroxide TS, and boil: the gas evolved turns a moistened red litmus paper blue.

- (2) Dissolve 0.05 g of Ethosuximide in 1 mL of ethanol (95), add 3 drops of a solution of copper (II) acetate monohydrate (1 in 100), warm slightly, and add 1 to 2 drops of sodium hydroxide TS: a purple color is produced.
- (3) Determine the absorption spectrum of a solution of Ethosuximide in ethanol (95) (1 in 2000) 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 wavelengths.

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

- (2) Chloride—With 1.0 g of Ethosuximide, perform the test. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.011%).
- (3) Heavy metals—Proceed with 1.0 g of Ethosuximide 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).
- (4) Arsenic—Prepare the test solution with 1.0 g of Ethosuximide, according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).
- (5) Acid anhydride—Dissolve 0.50 g of Ethosuximide in 1 mL of ethanol (95), add 1 mL of hydroxylammonium chloride-iron (III) chloride TS, and allow to stand for 5 minutes. Add 3 mL of water, mix, and allow to stand for 5 minutes: the red to red-purple color of this solution is not more intense than that of the following control solution.

Control solution: Dissolve 0.070 g of succinic anhydride in ethanol (95) to make exactly 100 mL. To 1.0 mL of this solution add 1 mL of hydroxylammonium chloride-iron (III) chloride TS, and proceed in the same manner.

(6) Cyanide—Dissolve 1.0 g of Ethosuximide in 10 mL of ethanol (95), and add 3 drops of iron (II) sulfate TS, 1 mL of sodium hydroxide TS and 2 to 3 drops of iron (III) chloride TS. Warm gently, and acidify with dilute sulfuric acid: not a blue precipitate and a blue color are produced within 15 minutes.

Water Not more than 0.5% (2 g, direct titration).

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

Assay Weigh accurately about 0.2 g of Ethosuximide, dissolve in 20 mL of N,N-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide VS (potentiometric titration). Perform a blank determination.

Each mL of 0.1 mol/L tetramethylammonium hydroxide VS

Containers and storage Containers—Tight containers.

 $= 14.117 \text{ mg of } C_7H_{11}NO_2$ 

## **Ethyl Aminobenzoate**

## Anesthamine Benzocaine

アミノ安息香酸エチル

 $C_9H_{11}NO_2$ : 165.19 Ethyl 4-aminobenzoate [94-09-7]

Ethyl Aminobenzoate, when dried, contains not less than 99.0% of  $C_9H_{11}NO_2$ .