red color develops, then add 2.0 mL of Standard Lead Solution, 2 mL of dilute acetic acid and water to make 50 mL (not more than 20 ppm).

(3) Related substances—Dissolve 0.010 g of Pentobarbital Calcium in 100 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 µL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the areas of each peak by the automatic integration method: the area of any peak other than the peak of pentobarbital from the sample solution is not bigger than 3/10 of the peak area of pentobarbital from the standard solution, and the total of these peak area is not bigger than the peak area of pentobarbital from the standard solution.

**Operating conditions**—

Detector, column, column temperature, mobile phase, and flow rate: Proceed as directed in the operating conditions in the Assay.

Time span of measurement: About 3 times as long as the retention time of pentobarbital after the solvent peak.

**System suitability**—

Test for required detection: Pipet 2 mL of the standard solution, add water to make exactly 20 mL, and confirm that the peak area of pentobarbital obtained from 20 µL of this solution is equivalent to 5 to 15% of that of pentobarbital obtained from 20 µL of the standard solution.

System performance: Proceed as directed in the system performance in the Assay.

System repeatability: When the test is repeated 6 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of pentobarbital is not more than 5%.

**Loss on drying** Not more than 7.0% (1 g, 105°C, 5 hours).

**Assay** Weigh accurately about 0.02 g of Pentobarbital Calcium, dissolve in 5 mL of water, add exactly 5 mL of the internal standard solution and water to make 50 mL. To 5 mL of this solution add water to make 20 mL. To 2 mL of this solution add water to make 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.018 g of Pentobarbital Reference Standard, previously dried at 105°C for 2 hours, dissolve in 10 mL of acetonitrile, add exactly 5 mL of the internal standard solution and water to make 50 mL. To 5 mL of this solution add water to make 20 mL. To 2 mL of this solution add water to make 20 mL, and use this solution as the standard solution. Perform the test with 20 µL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q₁ and Q₂, of the peak area of pentobarbital to that of the internal standard.

Amount (mg) of C₂₀H₂₆Ca₇N₄O₈₅
= amount (mg) of Pentobarbital Reference Standard
× \( \frac{Q₁}{Q₂} \) \times 1.0841

**Internal standard solution**—Dissolve 0.2 g of isopropyl parahydroxybenzoate in 20 mL of acetonitrile, and add water to make 100 mL.

**Operating conditions**—

Detector: An ultraviolet absorption photometer (wavelength: 210 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 µm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 1.36 g of potassium dihydrogenphosphate in 1000 mL of water, and adjust to pH 4.0 with diluted phosphoric acid (1 in 10). To 650 mL of this solution add 350 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of pentobarbital is about 7 minutes.

**System suitability**—

System performance: When the procedure is run with 20 µL of the standard solution under the above operating conditions, pentobarbital and the internal standard are eluted in this order with the resolution between these peaks being not less than 5.

System repeatability: When the test is repeated 6 times with 20 µL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of pentobarbital to that of the internal standard is not more than 1.0%.

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

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**Pentoxysverine Citrate**

**Carbetapentane Citrate**

**Carbetapentene Citrate**

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C₂₀H₂₆NO₅·C₆H₅O₇: 525.59
2-(2-(Diethylamino)ethoxy)ethyl
1-phenylcyclopentanecarboxylate monocitrate [23142-01-0]

Pentoxysverine Citrate, when dried, contains not less than 98.5% of C₂₀H₂₆NO₅·C₆H₅O₇.

**Description** Pentoxysverine Citrate occurs as a white, crystalline powder.

It is very soluble in acetic acid (100), freely soluble in water and in ethanol (95), and practically insoluble in diethyl ether.

**Identification** (1) Dissolve 0.1 g of Pentoxysverine Citrate in 10 mL of water, and add 10 mL of Reinecke salt TS: a light red precipitate is formed.

(2) Determine the infrared absorption spectrum of Pentoxysverine Citrate, previously dried, as directed in the paste method under the Infrared Spectrophotometry, and com-
Peplomycin Sulfate

佩プロマイシン

C₆₁H₈₀N₁₄O₂₅S₂.H₂SO₄: 1571.67
N¹-[3-[(1S)-(1-Phenylethyl)amino]propyl]bleomycinamide monosulfate  [70384-29-1]

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

Description Peplomycin Sulfate occurs as a white to light yellowish white powder.
It is freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

Perphenazine

ペルフェナジン

C₂₁H₂₉ClN₄OS: 403.97
2-{[3-(2-Chlorophenothiazin-10-yl)propyl]piperazin-1-yl}ethanol  [58-39-9]

Perphenazine, when dried, contains not less than 98.5% of C₂₁H₂₉ClN₄OS.

Description Perphenazine occurs as white to light yellow crystals or crystalline powder. It is odorless, and has a bitter taste.
It is freely soluble in methanol and in ethanol (95), soluble in acetic acid (100), sparingly soluble in diethyl ether, and practically insoluble in water.
It dissolves in dilute hydrochloric acid.
It is gradually colored by light.

Identification (1) Dissolve 5 mg of Perphenazine in 5 mL of sulfuric acid: a red color, changing to deep red-purple upon warming, is produced.