Flow rate: Adjust the flow rate to 1.5 mL per minute.

Time span of measurement: About 4.3 times as long as the retention time of iopamidol.

System suitability—

System performance: Dissolve 1 mL of the sample solution and 0.010 g of *N,N'*bis[2-hydroxy-1-(hydroxymethyl) ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide in water to make 100 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, *N,N'*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide and iopamidol are eluted in this order with the resolution between these peaks being not less than 7.

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 *N,N'*-bis[2-hydroxy-1-(hydroxymethyl)ethyl]-5-hydroxyacetylamino-2,4,6-triiodoisophthalamide is not more than 1.0%.

Loss on drying Not more than 0.30% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.5 g of Iopamidol, previously dried, transfer to a saponification flask, dissolve in 40 mL of sodium hydroxide TS, add 1 g of zinc powder, boil for 30 minutes under a reflux confenser, cool, and filter. Wash the flask and the filter paper with 50 mL of water, and combine the washing with the filtrate. Add 5 mL of acetic acid (100) to this solution, and titrate with 0.1 mol/L silver nitrate VS (potentiometric titration).

Each mL of 0.1 mol/L sliver nitrate VS
= 25.903 mg of $C_{17}H_{22}I_3N_3O_8$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Iopanoic Acid

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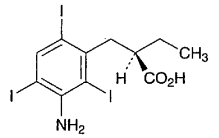

and enantiomer

$C_{11}H_{12}I_3NO_2$: 570.93

(*RS*)-2-(3-Amino-2,4,6-triiodobenzyl)butanoic acid

[*96-83-3*]

Iopanoic Acid, when dried, contains not less than 98.0% of $C_{11}H_{12}I_3NO_2$.

Description Iopanoic Acid occurs as a light yellowish white, crystalline powder. It has a faint, characteristic odor.

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

It dissolves in sodium hydroxide TS.

It is gradually colored by light.

Identification (1) Heat 0.1 g of Iopanoic Acid over a flame: a purple gas is evolved.

(2) Determine the infrared absorption spectrum of Iopanoic Acid, previously dried, as directed in the potassium bromide disk 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.

Melting point 152 - 158°C (with decomposition).

Purity (1) Soluble halides—Dissolve 2.5 g of Iopanoic Acid in 20 mL of water and 2.5 mL of ammonia TS, and add 20 mL of dilute nitric acid and water to make 100 mL. Allow the mixture to stand for 15 minutes with occasional shaking, and filter. Discard the first 10-mL portion of the filtrate, transfer the subsequent 25 mL of the filtrate to a Nessler tube, and add ethanol (95) to make 50 mL. Proceed as directed in the Chloride Limit Test using this solution as the test solution. Prepare the control solution as follows: to 0.10 mL of 0.01 mol/L hydrochloric acid VS add 6 mL of dilute nitric acid and water to make 25 mL, then add ethanol (95) to make 50 mL.

(2) Iodine—Dissolve 0.20 g of iopanoic Acid in 2.0 mL of sodium hydroxide TS, and 2.5 mL of 0.5 mol/L sulfuric acid TS, and allow to stand for 10 minutes with occasional shaking. Add 5 mL of chloroform, shake vigorously, and allow to stand: the chloroform layer remains colorless.

(3) Heavy metals—Proceed with 1.0 g of Iopanoic Acid 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).

(4) Arsenic—Prepare the test solution with 1.0 g of Iopanoic Acid according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

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

Assay Weigh accurately about 0.4 g of Iopanoic Acid, previously dried, and add 1 g of zinc powder and 10 mL of acetic acid (100). Boil for 30 minutes under a reflux condenser, add 30 mL of water through the condenser, and filter through absorbent cotton. Wash the flask and the cotton with two 20-mL portions of water, and combine the filtrate and washings. After cooling, titrate with 0.1 mol/L silver nitrate VS until the color of the precipitate changes from yellow to green (indicator: 1 mL of tetrabromophenolphthalein ethyl ester TS).

Each mL of 0.1 mol/L silver nitrate VS
= 19.031 mg of $C_{11}H_{12}I_3NO_2$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Iopanoic Acid Tablets

イオパノ酸錠

Iopanoic Acid Tablets contain not less than 95% and not more than 105% of the labeled amount of