Protamine Injection (Aqueous Suspension), equivalent to about 200 Units according to the labeled units, add 1 mL of 0.1 mol/L hydrochloric acid TS and sufficient water to make exactly 200 mL, dilute with water to contain 0.6 to 1.0 μg of zinc (Zn: 65.39) in 1 mL, and use this solution as the sample solution. Separately, pipet a volume of Standard Zinc Solution for the Atomic Absorption Spectrophotometry, dilute with water to contain 0.4 to 1.2 μg of zinc (Zn: 65.39) per ml, and use this solution as the standard solution. Perform the test with the sample solution and the standard solution according to the Atomic Absorption Spectrophotometry under the following conditions, and determine the amount of zinc in the sample solution using the analytical curve obtained from the absorbance of the standard solution.

Gas: Combustible gas—Acetylene gas
Supporting gas—Air
Lamp: Zinc hollow-cathode lamp
Wavelength: 213.9 nm

Containers and storage Containers—Hermetic containers.
Storage—In a cold place, and avoid freezing.

Expiration date 24 months after preparation.

Iodamide

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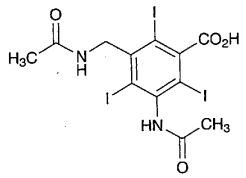

$C_{12}H_{11}I_3N_2O_4$: 627.94
3-Acetylamino-5-acetylaminomethyl-2,4,6-triiodobenzoic acid [*440-58-4*]

Iodamide, calculated on the dried basis, contains not less than 98.5% of $C_{12}H_{11}I_3N_2O_4$.

Description Iodamide occurs as a white, crystalline powder. It is odorless.

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

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

It gradually changes in color by light.

Identification **(1)** To 0.01 g of Iodamide add 5 mL of hydrochloric acid, and heat in a water bath for 5 minutes: the solution responds to the Qualitative Tests for primary aromatic amines.

(2) Heat 0.1 g of Iodamide over a flame: a purple gas evolves.

(3) Determine the infrared absorption spectrum of Iodamide, 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. If any difference appears between the spectra, dissolve 1 g of Iodamide in 100 mL of water by heating, and concentrate the solution to about 30 mL by gentle boiling. After cooling, collect the formed crystals by filtration, dry, and repeat the test on the dried crystals.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Iodamide in 10 mL of diluted sodium hydroxide TS (1 in 5): the solution is clear and colorless.

(2) Primary aromatic amines—Dissolve 0.20 g of Iodamide in 5 mL of water and 1 mL of sodium hydroxide TS, add 4 mL of a solution of sodium nitrite (1 in 100) and 10 mL of 1 mol/L hydrochloric acid TS, shake well, and allow to stand for 2 minutes. To this solution add 5 mL of ammonium amidosulfate TS, shake thoroughly, allow to stand for 1 minute, add 0.4 mL of a solution of 1-naphthol in ethanol (95) (1 in 10), 15 mL of sodium hydroxide TS and water to make exactly 50 mL, and determine the absorbance at 485 nm as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared in the same manner, as the blank: the absorbance of the solution is not more than 0.12.

(3) Soluble halide—Dissolve 2.5 g of Iodamide in 20 mL of water and 2.5 mL of ammonia TS, then add 20 mL of dilute nitric acid and water to make 100 mL. Allow to stand for 15 minutes with occasional shaking, and filter. Discard the first 10 mL of the filtrate, transfer 25 mL of the subsequent filtrate to a Nessler tube, and add ethanol (95) to make 50 mL. Use this solution as the test solution, and proceed as directed under the Chloride Limit Test. Prepare the control solution with 0.10 mL of 0.01 mol/L hydrochloric acid VS and 6 mL of dilute nitric acid, and dilute with water to 25 mL, then with ethanol (95) to 50 mL.

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

(5) Heavy metals—Proceed with 2.0 g of Iodamide according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

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

Loss on drying Not more than 3.0% (1 g, 105°C, 4 hours).

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

Assay Weigh accurately about 0.5 g of Iodamide in a saponification flask, dissolve in 40 mL of sodium hydroxide TS, add 1 g of zinc powder, connect the flask with a reflux condenser, boil for 30 minutes, cool, and filter. Wash the flask and filter paper with 50 mL of water, and combine the washings with the filtrate. Add 5 mL of acetic acid (100), and 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
= 20.931 mg of $C_{12}H_{11}I_3N_2O_4$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.