

*N*¹-{4-[3-(Guanidinobutyl)guanidino]butyl}-
bleomycinamide sulfate
[9041-93-4, Bleomycin Sulfate]

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

Description Bleomycin Sulfate occurs as a white to yellowish white powder.

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

Boric Acid

ホウ酸

H₃BO₃: 61.83

Boric Acid, when dried, contains not less than 99.5% of H₃BO₃.

Description Boric Acid occurs as colorless or white crystals or crystalline powder. It is odorless, and has a slight, characteristic taste.

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

The pH of a solution of Boric Acid (1 in 20) is between 3.5 and 4.1.

Identification A solution of Boric acid (1 in 20) responds to the Qualitative Tests for borate.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Boric acid in 25 mL of water or in 10 mL of hot ethanol (95): the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g of Boric Acid according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Arsenic—Prepare the test solution with 0.40 g of Boric Acid according to Method 1, and perform the test using Apparatus B (not more than 5 ppm).

Loss on drying Not more than 0.5% (2 g, silica gel, 5 hours).

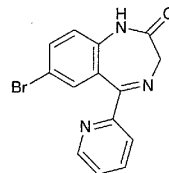
Assay Weigh accurately about 1.5 g of Boric Acid, previously dried, add 15 g of D-sorbitol and 50 mL of water, and dissolve by warming. After cooling, titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 1 mol/L sodium hydroxide VS
= 61.83 mg of H₃BO₃

Containers and storage Containers—Well-closed containers.

Bromazepam

ブロマゼパム



C₁₄H₁₀BrN₃O: 316.15

7-Bromo-1,3-dihydro-5-(pyridin-2-yl)-2H-1,4-benzodiazepin-2-one [1812-30-2]

Bromazepam, when dried, contains not less than 99.0% of C₁₄H₁₀BrN₃O.

Description Bromazepam occurs as white to light yellowish white crystals or crystalline powder. It is odorless.

It is freely soluble in *N,N*-dimethylformamide and in acetic acid (100), sparingly soluble in chloroform, slightly soluble in methanol and in ethanol (99.5), very slightly soluble in diethyl ether, and practically insoluble in water.

It dissolves in dilute hydrochloric acid.

Melting point: about 245°C (with decomposition).

Identification (1) Dissolve 0.01 g of Bromazepam in 5 mL of dilute hydrochloric acid, heat in a water bath for 10 minutes, and cool: the solution responds to the Qualitative Tests for primary aromatic amines.

(2) To 10 mL of a solution of Bromazepam in chloroform (1 in 10,000) add 5 mL of diluted iron (II) sulfate TS (1 in 8), and shake: a red-purple color develops in the water layer.

(3) Determine the absorption spectrum of a solution of Bromazepam in ethanol (99.5) (1 in 200,000) 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.

(4) To 0.3 g of Bromazepam in a porcelain crucible add 0.5 g of anhydrous sodium carbonate, stir well, and carbonize by ignition. After cooling, to the residue add 15 mL of hot water, heat on a water bath for 5 minutes, and filter. Render the filtrate slightly acidic with dilute hydrochloric acid: the solution responds to the Qualitative Tests for bromide.

Purity (1) Chloride—To 1.0 g of Bromazepam add 50 mL of water, allow to stand for 1 hour with occasional shaking, and filter. To 25 mL of the filtrate 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: to 0.25 mL of 0.01 mol/L hydrochloric acid VS add 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.018%).

(2) Heavy metals—Proceed with 1.0 g of Bromazepam in a platinum crucible according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Dissolve 1.0 g of Bromazepam in 15.0 mL of *N,N*-dimethylformamide. Perform the test with this solu-