Alimemazine Tartrate

酒石酸アリメマジン

 $(C_{18}H_{22}N_2S)_2.C_4H_6O_6$: 746.98 N, N-Dimethyl-N-[2-methyl-3-(phenothiazin-10-yl)propyl]amine hemitartrate [41375-66-0]

Alimemazine Tartrate, when dried, contains not less than 98.0% of $(C_{18}H_{22}N_2S)_2.C_4H_6O_6$.

Description Alimemazine Tartrate occurs as a white powder. It is odorless, and has a bitter taste.

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

The pH of a solution of Alimemazine Tartrate (1 in 50) is between 5.0 and 6.5.

It is gradually colored by light.

Identification (1) To 2 mL of a solution of Alimemazine Tartrate (1 in 100) add 1 drop of iron (III) chloride TS: a red-brown color is produced, and immediately a yellow precipitate is formed.

- (2) Dissolve 1 g of Alimemazine Tartrate in 5 mL of water, add 3 mL of sodium hydroxide TS, extract with two 10-mL portions of diethyl ether [use the aqueous layer obtained in the Identification (4)]. Shake the combined diethyl ether extracts with 3 g of anhydrous sodium sulfate, filter, and evaporate the diethyl ether with the aid of a current of air. Dry the residue in a desiccator (in vacuum, phosphorus (V) oxide) for 16 hours: it melts between 66°C and 70°C.
- (3) Determine the absorption spectrum of a solution of Alimemazine Tartrate (1 in 100,000) 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) The aqueous layer, obtained in the identification (2), when neutralized with dilute acetic acid, responds to the Qualitative Tests (1) and (2) for tartrate.

Melting point 159 – 163°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Alimemazine Tartrate in 20 mL of water: the solution is clear and colorless.

- (2) Heavy metals—Proceed with 1.0 g of Alimemazine Tartrate 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).
- (3) Arsenic—Prepare the test solution with 1.0 g of Alimemazine Tartrate according to Method 3, and perform the test using Apparatus B. Use a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 5) (not more than 2 ppm).

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 0.8 g of Alimemazine Tartrate, 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 red through brown to greenbrown (indicator: 2 mL of *p*-naphtholbenzein TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 37.350 mg of $(C_{18}H_{22}N_2S)_2.C_4H_6O_6$

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

Allopurinol

アロプリノール

 $C_5H_4N_4O$: 136.11 1*H*-Pyrazolo[3,4-*d*]pyrimidin-4-ol [315-30-0]

Allopurinol, when dried, contains not less than 98.0% of $C_5H_4N_4O$.

Description Allopurinol occurs as white to pale yellowish white crystals or crystalline powder. It is odorless.

It is slightly soluble in *N,N*-dimethylformamide, very slightly soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

It dissolves in sodium hydroxide TS and in ammonia TS. Melting point: not lower than 320°C (with decomposition).

Identification (1) Dissolve 0.1 g of Allopurinol in 50 mL of water by warming. To 5 mL of this solution add 1 mL of ammonia TS and 1 mL of silver nitrate TS: a white precipitate is produced.

- (2) Dissolve 0.1 g of Allopurinol in 50 mL of water by warming. To 5 mL of this solution add 0.5 mL of copper (II) sulfate TS: a blue precipitate is produced.
- (3) Determine the absorption spectrum of a solution of Allopurinol (1 in 200,000) as directed under the Ultravioletvisible 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 0.5 g of Allopurinol in 10 mL of sodium hydroxide TS: the solution is clear, and has no more color than Matching Fluid D.
- (2) Sulfate—To 2.0 g of Allopurinol add 100 mL of water, and boil for 5 minutes. Cool, add water to make 100 mL, and filter. To 25 mL of the filtrate add 1 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.038%).
- (3) Heavy metals—Proceed with 1.0 g of Allopurinol according to Method 2, and perform the test. Prepare the con-