

The concentration of Aminophylline Injection is expressed as the quantity of aminophylline ($C_{16}H_{24}N_{10}O_4 \cdot 2H_2O$: 456.46).

Method of preparation Prepare as directed under Injections, with Aminophylline. It may be prepared with Theophylline and its equivalent Ethylenediamine, instead of Aminophylline.

It may contain not more than 0.060 g of Ethylenediamine as a stabilizer for each g of Aminophylline.

Description Aminophylline Injection is a clear and colorless liquid. It has a slightly bitter taste.

It gradually changes in color by light.

pH: 8.0 - 10.0

Identification To a volume of Aminophylline Injection, equivalent to 0.75 g of Aminophylline according to the labeled amount, add water to make 30 mL. Proceed with this solution as directed in the Identification under Aminophylline.

Assay (1) Theophylline—To an accurately measured volume of Aminophylline Injection, equivalent to about 0.2 g of theophylline ($C_7H_8N_4O_2$) (about 0.25 g of Aminophylline), add 15 mL of water, 8 mL of ammonia TS and 20 mL of silver nitrate TS, and warm on a water bath for 15 minutes. Cool to between 5°C and 10°C for 20 minutes, filter the precipitate through a glass filter (G4), and wash with three 10-mL portions of water. Dissolve the precipitate in 5 mL of nitric acid, and wash the filter with three 10-mL portions of water. Combine the nitric acid solution and washings, and titrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS).

Each mL of 0.1 mol/L ammonium thiocyanate VS
= 18.017 mg of $C_7H_8N_4O_2$

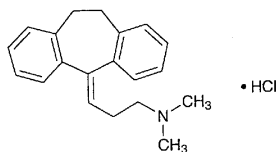
(2) Ethylenediamine—To an accurately measured volume of Aminophylline Injection, equivalent to about 0.03 g of ethylenediamine ($C_2H_8N_2$) (about 0.2 g of Aminophylline), add water to make 30 mL, and titrate with 0.1 mol/L hydrochloric acid VS (indicator: 2 to 3 drops of bromophenol blue TS).

Each mL of 0.1 mol/L hydrochloric acid VS
= 3.0049 mg of $C_2H_8N_2$

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

Amitriptyline Hydrochloride

塩酸アミトリプチリン



$C_{20}H_{23}N \cdot HCl$: 313.86

N-[3-(10,11-Dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-

ylidene)propyl]-*N,N*-dimethylamine monohydrochloride [549-18-8]

Amitriptyline Hydrochloride, when dried, contains not less than 99.0% of $C_{20}H_{23}N \cdot HCl$.

Description Amitriptyline Hydrochloride occurs as colorless crystals or a white to pale yellow crystalline powder. It has a bitter taste and a numbing effect.

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

The pH of a solution of Amitriptyline Hydrochloride (1 in 20) is between 4.0 and 5.0.

Identification (1) Dissolve 5 mg of Amitriptyline Hydrochloride in 3 mL of sulfuric acid: a red color develops. Add 5 drops of potassium dichromate TS to this solution: it turns dark brown.

(2) Acidify 1 mL of a solution of Amitriptyline Hydrochloride (1 in 500) with 0.5 mL of dilute nitric acid, and add 1 drop of silver nitrate TS: a white, opalescent precipitate is produced.

(3) Determine the absorption spectrum of a solution of Amitriptyline Hydrochloride (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Amitriptyline Hydrochloride Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

Melting point 195 - 198°C

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

(2) Heavy metals—Proceed with 2.0 g of Amitriptyline Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 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 0.5 g of Amitriptyline Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 31.387 mg of $C_{20}H_{23}N \cdot HCl$

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

Amitriptyline Hydrochloride Tablets

塩酸アミトリプチリン錠

Amitriptyline Hydrochloride Tablets contain not