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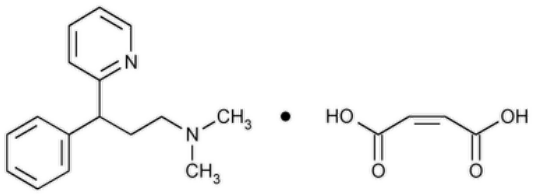
Pheniramine Maleate



$C_{16}H_{20}N_2 \cdot C_4H_4O_4$ 356.42

2-[α-[2-Dimethylaminoethyl]benzyl]pyridine bimaleate.

N,*N*-Dimethyl-3-phenyl-3-(2-pyridyl)propylamine hydrogen maleate CAS RN®: 132-20-7; UNII: NYW905655B.

» Pheniramine Maleate contains not less than 98.0 percent and not more than 102.0 percent of $C_{16}H_{20}N_2 \cdot C_4H_4O_4$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference Standards ⟨11⟩—
USP Pheniramine Maleate RS

Change to read:

Identification, ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Melting range, *Class I* ⟨741⟩**:** between 104° and 109°.

pH ⟨791⟩**:** between 4.5 and 5.5, in a solution (10 mg per mL).

Loss on drying ⟨731⟩—Dry it in vacuum at 65° for 6 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.5%.

Chromatographic purity—

0.005 M Octane sulfonic acid—Transfer 1.08 g of sodium 1-octane sulfonate to a 1-liter volumetric flask. Dilute with 1.5% (v/v) acetic acid solution to volume, add 5.0 mL of triethylamine, mix, and filter.

Mobile phase—Prepare a filtered and degassed mixture of *0.005 M Octane sulfonic acid* and acetonitrile (39:11). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

System suitability solution—Dissolve suitable quantities of phenylethyl alcohol and USP Pheniramine Maleate RS in water to obtain a solution containing about 3.6 and 0.24 mg per mL, respectively.

Test solution—Transfer about 24 mg of Pheniramine Maleate, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 265-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.5 phenylethyl alcohol and 1.0 for pheniramine maleate, and the resolution, *R,* between phenylethyl alcohol and pheniramine maleate is not less than 2.0, the tailing factor is not more than 2.5, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the percentage of each impurity (not including the solvent peak and maleic acid, if observed) in the portion of Pheniramine Maleate taken by the formula:

$$100(r_i/r_s)$$

in which r_i is the peak response for each impurity, and r_s is the sum of the responses of all of the peaks: not more than 0.5% of any individual impurity is found, and not more than 2.0% of total impurities is found.

Assay—Dissolve about 500 mg of Pheniramine Maleate, accurately weighed, in 25 mL of glacial acetic acid. Add 2 drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary corrections. Each mL of 0.1 N perchloric acid is equivalent to 17.82 mg of $C_{16}H_{20}N_2 \cdot C_4H_4O_4$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PHENIRAMINE MALEATE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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