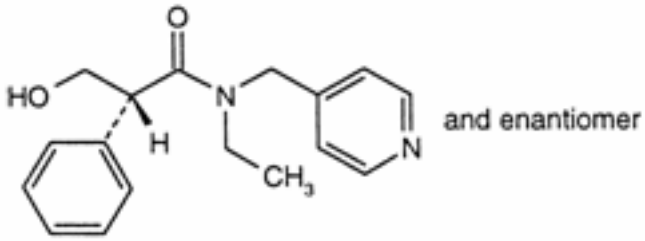
## Tropicamide (Tropicamidum)




$C_{17}H_{20}N_2O_2$

**Relative molecular mass.** 284.4

**Chemical name.** *N*-Ethyl-2-phenyl-*N*-(4-pyridylmethyl)hydracrylamide; *N*-ethyl-α-(hydroxymethyl)-*N*-(4-pyridinylmethyl)-benzeneacetamide; CAS Reg. No. 1508-75-4.

**Description.** A white or almost white, crystalline powder.

**Solubility.** Slightly soluble in water; freely soluble in dichloromethane R and ethanol (~750 g/l) TS.

**Category.** Mydriatic.

**Storage.** Tropicamide should be kept in a tightly closed container, protected from light.

**Labelling.** The designation Tropicamide for sterile non-injectable use indicates that the substance complies with the additional requirement and may be used for sterile applications. Expiry date.

### Requirements

Tropicamide contains not less than **99.0%** and not more than **101.0%** of $C_{17}H_{20}N_2O_2$, calculated with reference to the dried substance.

### Identity tests

• Either test A alone or tests B, C, and D may be applied.

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from tropicamide RS or with the *reference spectrum* of tropicamide.

B. The absorption spectrum of a 0.04 mg/mL solution in hydrochloric acid (0.1mol/l) VS, when observed between 230nm and 350nm, exhibits a maximum at about 254nm; the absorbance of a 1-cm layer at this wavelength is about 0.72.

C. Dissolve 5mg in 3ml of a mixture of 9 mL of acetic anhydride R, 1 mL of acetic acid (~300 g/l) TS, and 0.10 g of citric acid R. Heat on a water-bath for 5-10 minutes: a reddish yellow colour is produced.

D. Melting temperature, about 97 °C.

**Sulfated ash.** Not more than 1.0 mg/g.

**Loss on drying.** Dry at 80 °C under reduced pressure (not exceeding 0.6kPa or about 5 mm of mercury) for 4 hours; it loses not more than 5.0 mg/g.

**Tropic acid.** To 10.0mg add 5mg of sodium tetraborate R and 0.35 mL of a freshly prepared solution containing 1.0 g of dimethylaminobenzaldehyde R in 10ml of a mixture of 9 volumes of sulfuric acid (~1760 g/l) TS and 1 volume of water. Heat on a water-bath for 3 minutes. Cool in ice-water and add 5 mL of acetic anhydride R; no violet-red colour develops (0.05%).

**Related substances.** Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R4 as the coating substance and a mixture of 95 volumes of dichloromethane R, 5 volumes of methanol R, and 0.5 volume of ammonia (~260g/l) TS as the mobile phase. Apply separately to the plate 10µl of each of 3 solutions in dichloromethane R containing (A) 20mg of Tropicamide per mL, (B) 0.10 mg of Tropicamide per mL, and (C) 40µg of Tropicamide per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254 nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B (0.5%). Not more than one such spot is more intense than that obtained with solution C (0.2%).

**Assay.** Dissolve about 0.2 g, accurately weighed, in 50 mL of glacial acetic acid R1, and titrate with perchloric acid (0.1 mol/l) VS,

using 1-naphtholbenzein/ acetic acid TS as indicator until the colour changes from orange to green as described under 2.6 Non-aqueous titration, Method A.

Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 28.44mg of $C_{17}H_{20}N_2O_2$.

***Additional requirement for sterile non-injectable Tropicamide***

Complies with 3.2 Test for sterility.