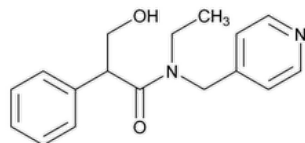


Status: Currently Official on 17-Feb-2025  
 Official Date: Official as of 01-May-2020  
 Document Type: USP Monographs  
 DocId: GUID-8EEDB465-9B43-4BD0-AB9F-64AB6360D3EF\_4\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M86590\\_04\\_01](https://doi.org/10.31003/USPNF_M86590_04_01)  
 DOI Ref: zog14

© 2025 USPC  
 Do not distribute

# Tropicamide



$C_{17}H_{20}N_2O_2$  284.35

Benzeneacetamide, *N*-ethyl- $\alpha$ -(hydroxymethyl)-*N*-(4-pyridinylmethyl)-, ( $\pm$ );

*N*-Ethyl-3-hydroxy-2-phenyl-*N*-(pyridin-4-ylmethyl)propanamide CAS RN®: 1508-75-4; UNII: N0A3Z5XTC6.

## DEFINITION

Tropicamide contains NLT 98.0% and NMT 102.0% of tropicamide ( $C_{17}H_{20}N_2O_2$ ), calculated on the dried basis.

## IDENTIFICATION

**Change to read:**

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

## ASSAY

### PROCEDURE

**Buffer:** Dissolve 0.135 g of sodium dodecyl sulfate and 3.4 mL of phosphoric acid in 950 mL of water. Adjust with 10 M sodium hydroxide to a pH of 3.0, and dilute with water to 1000 mL.

**Mobile phase:** Acetonitrile and *Buffer* (27:73)

**Standard solution:** 0.15 mg/mL of [USP Tropicamide RS](#) prepared as follows. Transfer [USP Tropicamide RS](#) into a suitable volumetric flask, and add acetonitrile equivalent to 6% of the final volume to dissolve. Dilute with water to volume.

**Sample solution:** 0.15 mg/mL of Tropicamide prepared as follows. Transfer Tropicamide into a suitable volumetric flask, and add acetonitrile equivalent to 6% of the final volume to dissolve. Dilute with water to volume.

### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** 210 nm

**Column:** 4.6-mm  $\times$  15-cm; 3- $\mu$ m packing L1

**Column temperature:** 40°

**Flow rate:** 0.8 mL/min

**Injection volume:** 15  $\mu$ L

### System suitability

**Sample:** *Standard solution*

### Suitability requirements

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 0.73%

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of tropicamide ( $C_{17}H_{20}N_2O_2$ ) in the portion of Tropicamide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of tropicamide from the *Sample solution*

$r_S$  = peak response of tropicamide from the *Standard solution*

$C_S$  = concentration of [USP Tropicamide RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Tropicamide in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the dried basis

## IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

### • ORGANIC IMPURITIES

**Buffer and Mobile phase:** Proceed as directed in the Assay.

**System suitability stock solution 1:** 100 µg/mL each of [USP Tropicamide Related Compound A RS](#), [USP Tropicamide Related Compound C RS](#), and [USP Tropicamide Related Compound D RS](#) prepared as follows. Transfer [USP Tropicamide Related Compound A RS](#), [USP Tropicamide Related Compound C RS](#), and [USP Tropicamide Related Compound D RS](#) into a suitable volumetric flask, and add acetonitrile equivalent to 4% of the final volume to dissolve. Dilute with water to volume.

**System suitability stock solution 2:** 10 µg/mL each of [USP Tropicamide Related Compound A RS](#), [USP Tropicamide Related Compound C RS](#), and [USP Tropicamide Related Compound D RS](#) prepared as follows. Dilute 1 mL of *System suitability stock solution 1* with water to 10 mL.

**System suitability stock solution 3:** 0.5 mg/mL of [USP Tropicamide RS](#) and 20 µg/mL of [USP Tropicamide Related Compound B RS](#) prepared as follows. Transfer [USP Tropicamide RS](#) and [USP Tropicamide Related Compound B RS](#) into a suitable volumetric flask, and add acetonitrile equivalent to 10% of the final volume to dissolve. Dilute with water to volume.

**System suitability solution:** Mix 1 mL each of *System suitability stock solution 2* and *System suitability stock solution 3*.

**Standard stock solution:** 1 mg/mL of [USP Tropicamide RS](#) prepared as follows. Transfer [USP Tropicamide RS](#) into a suitable volumetric flask, and add acetonitrile equivalent to 6% of the final volume to dissolve. Dilute with water to volume.

**Standard solution 1:** 1 µg/mL of [USP Tropicamide RS](#) in water from *Standard stock solution*

**Standard solution 2:** 1.5 µg/mL each of [USP Tropicamide Related Compound C RS](#) and [USP Tropicamide Related Compound D RS](#) in water from *System suitability stock solution 1*

**Sample solution:** 1 mg/mL of Tropicamide prepared as follows. Transfer 50 mg of Tropicamide into a 50-mL volumetric flask, and add 3 mL of acetonitrile to dissolve. Dilute with water to volume.

## Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** 210 and 254 nm

**Column:** 4.6-mm × 15-cm; 3-µm packing L1

**Column temperature:** 40°

**Flow rate:** 0.8 mL/min

**Injection volume:** 15 µL

**Run time:** NLT 3 times the retention time of the tropicamide peak

## System suitability

**Sample:** *System suitability solution*

### Suitability requirements

**Resolution at 210 nm:** NLT 2 between the tropicamide related compounds C and A peaks; NLT 2 between the tropicamide related compounds A and D peaks

## Analysis

**Samples:** *Standard solution 1*, *Standard solution 2*, and *Sample solution*

Calculate the percentage of tropicamide related compound C and tropicamide related compound D in the portion of Tropicamide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of relevant tropicamide related compound from the *Sample solution* at 210 nm

$r_S$  = peak response of relevant tropicamide related compound from *Standard solution 2* at 210 nm

$C_S$  = concentration of relevant tropicamide related compound in *Standard solution 2* (mg/mL)

$C_U$  = concentration of Tropicamide in the *Sample solution* (mg/mL)