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Tropicamide Ophthalmic Solution

DEFINITION

Tropicamide Ophthalmic Solution is a sterile, aqueous solution of Tropicamide. It contains NLT 95.0% and NMT 105.0% of the labeled amount of tropicamide ($C_{17}H_{20}N_2O_2$). It contains a suitable antimicrobial agent, and may contain suitable substances to increase its viscosity.

IDENTIFICATION

Change to read:

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

Sample: Extract 10 mL of Ophthalmic Solution with 25 mL of chloroform, pass the chloroform extract through dry, folded filter paper, and evaporate the filtrate to dryness.

Acceptance criteria: The residue so obtained meets the requirements.

• **B.** The UV absorption spectrum of the solution used for measurement of absorbance in the *Assay* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Tropicamide RS, concomitantly measured.

ASSAY

• **Procedure**

Standard solution: 30 µg/mL of USP Tropicamide RS in dilute sulfuric acid (1 in 6)

Sample solution: Transfer a volume of Ophthalmic Solution, nominally equivalent to 30 mg of tropicamide, to a 100-mL volumetric flask, and add water to volume. Transfer 10.0 mL of this solution to a separator, add 2 mL of sodium carbonate solution (1 in 10), extract with four 20-mL portions of chloroform, and combine the extracts in a second separator. Wash the combined extracts with a 25-mL portion of pH 6.5 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*), and transfer to another separator. Wash the aqueous layer with 10 mL of chloroform, and add it to the extracts. Extract the chloroform solution with four 20-mL portions of dilute sulfuric acid (1 in 6), combine the acid extracts in a 100-mL volumetric flask, and add the dilute acid to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: At the wavelength of maximum absorbance at about 253 nm

Cell: 1 cm

Blank: Dilute sulfuric acid (1 in 6)

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of the labeled amount of tropicamide ($C_{17}H_{20}N_2O_2$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Tropicamide RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of tropicamide in the *Sample solution* (µg/mL)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **pH ⟨791⟩:** 4.0–5.8

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and avoid freezing.
- **USP Reference Standards** ⟨11⟩

  USP Tropicamide RS

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

Topic/Question	Contact	Expert Committee
TROPICAMIDE OPHTHALMIC SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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