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Tretinoin Topical Solution

DEFINITION

Tretinoin Topical Solution is a solution of Tretinoin in a suitable nonaqueous, hydrophilic solvent. It contains NLT 90.0% and NMT 135.0% of the labeled amount of tretinoin ($C_{20}H_{28}O_2$) (w/w).

IDENTIFICATION

• A.

Sample solution: Mix 5 mL of Topical Solution and 5 mL of water.

Acceptance criteria: A voluminous yellow precipitate is formed.

• B.

Sample solution: Proceed as directed for the *Sample solution* in the *Assay*.

Analysis: Measure the absorbance between 300 and 450 nm.

Acceptance criteria: The *Sample solution* exhibits maxima and minima at the same wavelengths as that of a similar solution of [USP Tretinoin RS](#), concomitantly measured.

ASSAY

• PROCEDURE

Avoid exposure to strong light, and use low-actinic glassware.

Acidified isopropyl alcohol: Dilute 1 mL of 0.01 N hydrochloric acid with isopropyl alcohol to make 1000 mL.

Standard solution: 3.75 μ g/mL of [USP Tretinoin RS](#) in Acidified isopropyl alcohol

Sample solution: Nominally 3.75 μ g/mL of tretinoin in Acidified isopropyl alcohol from Topical Solution

Instrumental conditions

Mode: UV

Analytical wavelength: 352 nm

Cell: 1 cm

Blank: Acidified isopropyl alcohol

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of tretinoin ($C_{20}H_{28}O_2$) in the portion of Topical 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 Tretinoin RS](#) in the *Standard solution* (μ g/mL)

C_U = nominal concentration of tretinoin in the *Sample solution* (μ g/mL)

Acceptance criteria: 90.0%–135.0%

OTHER COMPONENTS

• [ALCOHOL DETERMINATION \(611\)](#): 90.0%–110.0% of the labeled amount of alcohol (C_2H_5OH)

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP REFERENCE STANDARDS \(11\)](#).

[USP Tretinoin RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TRETINOIN TOPICAL 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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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