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Tretinoin Cream

DEFINITION

Tretinoin Cream contains NLT 90.0% and NMT 120.0% of the labeled amount of tretinoin ($C_{20}H_{28}O_2$).

IDENTIFICATION

- **A.** 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

Avoid exposure to strong light, and use low-actinic glassware in the performance of the following procedure. Use stabilized tetrahydrofuran in the preparation of the *Standard solution* and the *Sample solution*.

Diluted phosphoric acid: Dilute 10 mL of phosphoric acid with water to 100 mL.

Buffer: 1.38 g/L of monobasic sodium phosphate in water. Adjust with *Diluted phosphoric acid* to a pH of 3.0.

Diluent A: Water and *Diluted phosphoric acid* (9:1)

Diluent B: Tetrahydrofuran and *Diluent A* (3:2)

Mobile phase: Tetrahydrofuran and *Buffer* (42:58)

Standard stock solution: 0.4 mg/mL of [USP Tretinoin RS](#) in tetrahydrofuran

Standard solution: 4 µg/mL of [USP Tretinoin RS](#) in *Diluent B* from *Standard stock solution*

Sample stock solution: Nominally 20 µg/mL of tretinoin in tetrahydrofuran prepared as follows. Transfer a quantity of Cream, equivalent to 1.0 mg of tretinoin, into a 50-mL volumetric flask, and add 20.0 mL of tetrahydrofuran. Shake the flask to disperse the cream, dilute with tetrahydrofuran to volume, mix, and filter if necessary.

Sample solution: 4 µg/mL of tretinoin in *Diluent B* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 365 nm

Column: 3.9-mm × 15-cm; 4-µm packing L1

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

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 Cream taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or 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 CREAM	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:

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