

Status: Currently Official on 17-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-A2E8DAD2-437E-4D7A-B5D7-45239C3557A3_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M84540_01_01
 DOI Ref: eag8k

© 2025 USPC
 Do not distribute

Tretinoin Gel

DEFINITION

Tretinoin Gel contains NLT 90.0% and NMT 130.0% of the labeled amount of $C_{20}H_{28}O_2$.

IDENTIFICATION

The retention time of the major peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

[NOTE—Avoid exposure to strong light, and use low-actinic glassware in the performance of the following procedure.]

Mobile phase: Prepare a mixture of acetonitrile and water (17:3). Add 5 mL of glacial acetic acid to each L of the mixture, mix well, filter, and degas.

Standard solution: 0.02 mg/mL of [USP Tretinoin RS](#) in methanol. [NOTE—Sonicate if needed.]

Sample solution: Transfer Tretinoin Gel, equivalent to 2 mg of tretinoin, to a 100-mL volumetric flask. Add about 70 mL of methanol, sonicate with intermittent shaking for 30 min, and dilute with methanol to volume. Centrifuge a portion of this solution at 3000 rpm for 10 min. Use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 353 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Flow rate: 1.5 mL/min

Injection size: 20 μL

Autosampler temperature: 15°

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Tailing factor: NMT 2.0

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{20}H_{28}O_2$ in the portion of Gel 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%–130.0%

PERFORMANCE TESTS

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

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light.
- **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 GEL	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. PF 42(1)

Current DocID: GUID-A2E8DAD2-437E-4D7A-B5D7-45239C3557A3_1_en-US

DOI: https://doi.org/10.31003/USPNF_M84540_01_01

DOI ref: [eag8k](#)

OFFICIAL