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Delete the following:

▲Rimexolone Ophthalmic Suspension

DEFINITION

Rimexolone Ophthalmic Suspension is a sterile suspension of Rimexolone in a suitable aqueous medium. It contains NLT 90.0% and NMT 110.0% of the labeled amount of rimexolone ($C_{24}H_{34}O_3$). It may contain suitable stabilizers, buffers, and antimicrobial agents.

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**

Mobile phase: Acetonitrile and water (60:40)

Standard stock solution: 1 mg/mL of USP Rimexolone RS in methanol

Standard solution: 0.2 mg/mL of USP Rimexolone RS in *Mobile phase* from *Standard stock solution*

Sample stock solution: Nominally 1 mg/mL of rimexolone, prepared as follows. Transfer an amount nominally equivalent to 25 mg of rimexolone from a portion of Ophthalmic Suspension to a 25-mL volumetric flask. Dilute with methanol to volume and sonicate for 2 min.

Sample solution: Nominally 0.2 mg/mL of rimexolone from the *Sample stock solution* in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, *k'*: NLT 1.5

Column efficiency: NLT 3000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rimexolone ($C_{24}H_{34}O_3$) in the portion of Ophthalmic Suspension 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 Rimexolone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Sterility Tests ⟨71⟩:** Meets the requirements
- **pH ⟨791⟩:** 6.0–8.0
- **Viscosity—Rotational Methods ⟨912⟩**

  Analysis: Equip a cone-and-plate rheometer[1] following *Method III*. The shear rate under the test condition is 11.5 s^{-1} and temperature is 25°.

  Acceptance criteria: 15–200 mPa · s

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards ⟨11⟩**

  USP Rimexolone RS▲ (USP 1-Dec-2024)

[1] Brookfield cone-and-plate rheometer, with spindle CP-42 (#42), is operated at 3 rpm. Any other equivalent rheometer is suitable as well.

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

Topic/Question	Contact	Expert Committee
RIMEXOLONE OPHTHALMIC SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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