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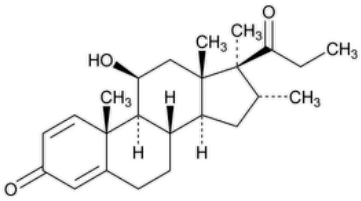
Delete the following:

▲Rimexolone



$C_{24}H_{34}O_3$ 370.52

Androsta-1,4-diene-3-one, 11-hydroxy-16,17-dimethyl-17-(1-oxopropyl)-, (11β,16α,17β)-;

11β-Hydroxy-16α,17α-dimethyl-17-propionylandrosta-1,4-diene-3-one CAS RN®: 49697-38-3; UNII: O7M2E4264D.

DEFINITION

Rimexolone contains NLT 97.0% and NMT 102.0% of rimexolone ($C_{24}H_{34}O_3$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

• **B. Thin-Layer Chromatography**

Standard solution: 10 mg/mL of USP Rimexolone RS in chloroform

Sample solution: 10 mg/mL of rimexolone in chloroform

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of silica gel mixture

Application volume: 5 µL

Developing solvent system: Chloroform and methanol (19:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the samples to the thin-layer chromatographic plate. Develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Observe the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the principal spot of the *Standard solution*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (6:4)

Standard solution: 0.2 mg/mL of USP Rimexolone RS, prepared by dissolving a suitable quantity in methanol and diluting with *Mobile phase* to volume

Sample stock solution: 1 mg/mL of Rimexolone in methanol

Sample solution: 0.2 mg/mL of Rimexolone diluted with *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 25-cm; 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 rimexolone ($C_{24}H_{34}O_3$) in the portion of Rimexolone 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 = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Mobile phase: Prepare as directed in the *Assay*.

Standard solution: Use the *Standard solution* prepared in the *Assay*.

Sample stock solution: 1 mg/mL of Rimexolone in methanol

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

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 25-cm; 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

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Rimexolone taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria

Individual impurities: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation* ⟨781S⟩
  Sample solution: 20 mg/mL in chloroform
  Acceptance criteria: +47° to +54°
- **Loss on Drying** ⟨731⟩
  Analysis: Dry a sample under vacuum at 105° for 3 h.
  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Rimexolone RS▲ (USP 1-Dec-2024)

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

Topic/Question	Contact	Expert Committee
RIMEXOLONE	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(3)

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