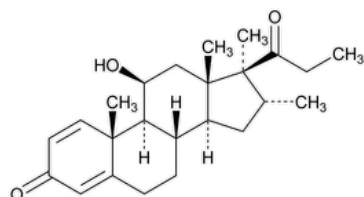


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Delete the following:

^Rimexolone



$C_{24}H_{34}O_3$

370.52

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

11 β -Hydroxy-16 α ,17 α -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 μ L

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 $\times$ 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 μ L

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**