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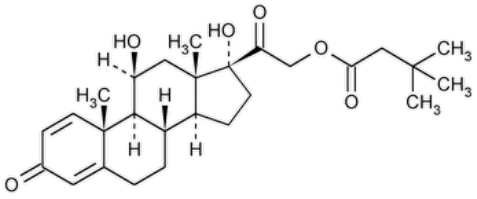
Prednisolone Tebutate

Change to read:



$C_{27}H_{38}O_6$ ▲(USP 1-Aug-2022) 458.59

Pregna-1,4-diene-3,20-dione, 11,17-dihydroxy-21-(3,3-dimethyl-1-oxobutyl)oxy-, (11β)-;

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-(3,3-dimethylbutyrate) CAS RN®: 7681-14-3; UNII: 1V7A1U282K.

DEFINITION

Prednisolone Tebutate contains NLT 97.0% and NMT 103.0% of prednisolone tebutate ($C_{27}H_{38}O_6$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- ▲**A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197M▲(USP 1-Aug-2022)

  Sample: Dissolve a portion of Prednisolone Tebutate in acetone and evaporate to dryness, then dry at a pressure not exceeding 5 mm of mercury at 105° for 4 h.

  Acceptance criteria: ▲Meets the requirements▲(USP 1-Aug-2022)

- **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

  Analytical wavelength: 242 nm

  Sample solution: 20 µg/mL in methanol

  Acceptance criteria: Absorptivities, calculated on the dried basis, differ by NMT 3.0%

ASSAY

Change to read:

- **Procedure**

  Mobile phase: Isooctane, tetrahydrofuran, and alcohol (89:10:1)

  Diluent: Isooctane and tetrahydrofuran (50:50)

  Standard solution: 1 mg/mL of USP Prednisolone Tebutate RS in *Diluent*

  Sample solution: 1 mg/mL of Prednisolone Tebutate in *Diluent*

  Chromatographic system

  ▲(See *Chromatography ⟨621⟩, System Suitability*.)▲(USP 1-Aug-2022)

  Mode: LC

  Detector: UV 254 nm

  Column: 3.9-mm × 30-cm; packing L3

  Column temperature: 25°

  Flow rate: 1.0 mL/min

  Injection volume: 25 µL

  Run time: NLT 1.5 times the retention time of prednisolone tebutate

  System suitability

  Sample: *Standard solution*

[NOTE—The retention time for prednisolone tebutate is about 30 min.]

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prednisolone tebutate ($C_{27}H_{38}O_6$) in the portion of Prednisolone Tebutate taken:

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

r_U = peak area of prednisolone tebutate from the *Sample solution*

r_S = peak area of prednisolone tebutate from the *Standard solution*

C_S = concentration of USP Prednisolone Tebutate RS in the *Standard solution* (mg/mL)

C_U = concentration of Prednisolone Tebutate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%

Delete the following:

▲• **SELENIUM ⟨291⟩**

Sample: 200 mg of Prednisolone Tebutate

Acceptance criteria: 0.003%▲ (USP 1-Aug-2022)

SPECIFIC TESTS

• **OPTICAL ROTATION ⟨781S⟩, *Procedures, Specific Rotation***

Sample solution: 10 mg/mL in chloroform

Acceptance criteria: +100° to +115°

• **LOSS ON DRYING ⟨731⟩**

Analysis: Dry at a pressure not exceeding 5 mm of mercury at 105° for 4 h.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers sealed under sterile nitrogen, in a cold place.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Prednisolone Tebutate RS

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

Topic/Question	Contact	Expert Committee
PREDNISOLONE TEBUTATE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(1)

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