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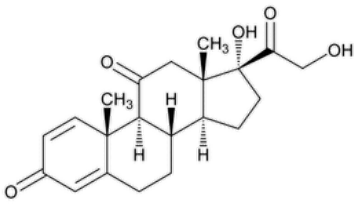
Prednisone



$C_{21}H_{26}O_5$ 358.44

Pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy-;

17,21-Dihydroxypregna-1,4-diene-3,11,20-trione CAS RN®: 53-03-2; UNII: VB0R961HZT.

DEFINITION

Prednisone contains NLT 97.0% and NMT 102.0% of prednisone ($C_{21}H_{26}O_5$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Analysis: If a difference appears, dissolve portions of both the sample and the Reference Standard in methanol, evaporate the solutions to dryness, and repeat the tests.

Acceptance criteria: Meets the requirements

• **B.**

Analysis 1: Dissolve 6 mg in 2 mL of sulfuric acid, and allow to stand for 5 min.

Acceptance criteria 1: An orange color is produced.

Analysis 2: Pour the resulting solution from *Analysis 1* into 10 mL of water.

Acceptance criteria 2: The color changes first to yellow and then, gradually, to bluish green.

ASSAY

• **Procedure**

Mobile phase: Peroxide-free tetrahydrofuran, methanol, and water (250:62:688)

Diluent: Methanol and water (1:1)

Standard stock solution: 0.2 mg/mL of USP Prednisone RS in *Diluent*

Internal standard solution: 110 µg/mL of acetanilide in *Diluent*

Standard solution: 20 µg/mL of USP Prednisone RS and 11 µg/mL of acetanilide in *Diluent* from the *Standard stock solution* and the *Internal standard solution*, respectively. Prepare this solution fresh.

Sample stock solution: 0.2 mg/mL of Prednisone in *Diluent*

Sample solution: 20 µg/mL of Prednisone and 11 µg/mL of acetanilide in *Diluent* from the *Sample stock solution* and the *Internal standard solution*, respectively. Prepare this solution fresh.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 25-cm; packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention times of acetanilide and prednisone are about 6 and 8 min, respectively.]

Suitability requirements

Resolution: NLT 3 between prednisone and acetanilide

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prednisone ($C_{21}H_{26}O_5$) in the portion of Prednisone taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of prednisone to acetanilide from the *Sample solution*

R_S = peak response ratio of prednisone to acetanilide from the *Standard solution*

C_S = concentration of USP Prednisone RS in the *Standard solution* (µg/mL)

C_U = concentration of Prednisone in the *Sample solution* (µg/mL)

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

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩**

Sample: 100 mg

Acceptance criteria: Negligible

• **ORGANIC IMPURITIES**

Mobile phase: Chloroform and methanol (98:2)

Sample solution: 1.25 mg/mL of Prednisone in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 6.0-mm × 4.0-cm; packing L3

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Sample: *Sample solution*

Suitability requirements

Column efficiency: NLT 2500 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Prednisone 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

Any individual impurity: NMT 1.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

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

Sample solution: 5 mg/mL in dioxane

Acceptance criteria: +167° to +175°

• **WATER DETERMINATION,** *Method I ⟨921⟩*

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light and moisture. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

  USP Prednisone RS

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

Topic/Question	Contact	Expert Committee
PREDNISONE	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

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