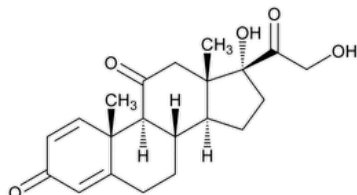


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-AB76AFBC-BD2F-42DE-80AD-395AD87010F9_2_en-US
DOI: https://doi.org/10.31003/USPNF_M68910_02_01
DOI Ref: mvi4o

© 2025 USPC
Do not distribute

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%