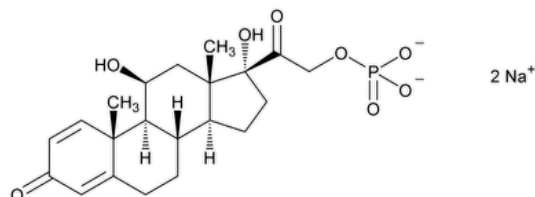


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Prednisolone Sodium Phosphate



$C_{21}H_{27}Na_2O_8P$ 484.39

Pregna-1,4-diene-3,20-dione, 11,17-dihydroxy-21-(phosphonoxy)-, disodium salt, (11 β);

11 β ,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-(disodium phosphate) CAS RN®: 125-02-0; UNII: IV021NXA9J.

DEFINITION

Prednisolone Sodium Phosphate contains NLT 96.0% and NMT 102.0% of prednisolone sodium phosphate ($C_{21}H_{27}Na_2O_8P$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K
- **B. IDENTIFICATION TESTS—GENERAL** (191), *Chemical Identification Tests, Sodium* and *IDENTIFICATION TESTS—GENERAL* (191), *Chemical Identification Tests, Phosphate*

Sample: The residue from the ignition of 20 mg of Prednisolone Sodium Phosphate

Acceptance criteria: Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Buffer solution: Transfer 6.6 g of [hexylamine](#) and 5.32 g of [monobasic ammonium phosphate](#) into an appropriate flask. After 10 min, add 1850 g of [water](#) and dissolve the contents while stirring. Adjust with [phosphoric acid](#) to a pH of 6.40 ± 0.05 .

Mobile phase: To the entire quantity of *Buffer solution* prepared above add 390 g of [acetonitrile](#), mix by stirring, and then sonicate for NMT 2 min.

System suitability solution: 0.01 mg/mL each of [USP Prednisolone RS](#) and [USP Prednisolone Sodium Phosphate RS](#) in *Mobile phase*

Standard solution: 0.3 mg/mL of [USP Prednisolone RS](#) in *Mobile phase*

Sample solution: 0.42 mg/mL of Prednisolone Sodium Phosphate in *Mobile phase*

Chromatographic system

(See [Chromatography](#) (621), *System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm $\times$ 7.5-cm; 3.5- μ m packing [L1](#)

Temperatures

▲Autosampler: ▲ (USP 1-Aug-2022) 6°

Column: 35°

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

Run time: ▲NLT 1.6 times the retention time of prednisolone sodium phosphate ▲ (USP 1-Aug-2022)

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for prednisolone and prednisolone sodium phosphate are about 0.52 and 1, respectively.]

Suitability requirements

Resolution: NLT 12 between prednisolone and prednisolone sodium phosphate, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prednisolone sodium phosphate ($C_{21}H_{27}Na_2O_8P$) in the portion of Prednisolone Sodium Phosphate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of prednisolone sodium phosphate from the *Sample solution*

r_S = peak response of prednisolone from the *Standard solution*

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

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

M_{r1} = molecular weight of prednisolone sodium phosphate, 484.39

M_{r2} = molecular weight of prednisolone, 360.45

Acceptance criteria: 96.0%–102.0% on the anhydrous basis

IMPURITIES

Delete the following:

▲ • [SELENIUM \(291\)](#)

Sample: 200 mg of Prednisolone Sodium Phosphate

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

Change to read:

• PHOSPHATE IONS

Solution A: 50 mg/mL of [ammonium molybdate](#) in 1 N [sulfuric acid](#)

Solution B: 3.5 mg/mL of [p-methylaminophenol sulfate](#) and 200 mg/mL of [sodium bisulfite](#) in [water](#) prepared as follows. Dissolve 350 mg of [p-methylaminophenol sulfate](#) in 50 mL of [water](#), add 20 g of [sodium bisulfite](#), mix and dissolve, then dilute with [water](#) to 100 mL.

Sample solution: Dissolve 50 mg of Prednisolone Sodium Phosphate in a mixture of 10 mL of [water](#) and 5 mL of ▲ [2 N sulfuric acid TS](#) ▲ (USP 1-Aug-2022) contained in a 25-mL volumetric flask, by warming, if necessary. Add 1 mL each of *Solution A* and *Solution B*, dilute with [water](#) to volume, and allow to stand at room temperature for 30 min.

Standard stock solution: 0.10 mg/mL of phosphate (PO_4) prepared as follows. Dissolve 143.3 mg of dried [monobasic potassium phosphate](#) (KH_2PO_4) in [water](#) to make 1000.0 mL.

Standard solution: Concomitantly prepare as directed for the *Sample solution*, using 5.0 mL of *Standard stock solution* instead of the 50 mg of Prednisolone Sodium Phosphate.

Instrumental conditions

Mode: Vis

Analytical wavelength: 730 nm

Cell: 1 cm

Blank: [Water](#)

Analysis:

Concomitantly determine the absorbances of the *Sample solution* and the *Standard solution*.

Acceptance criteria: The absorbance of the *Sample solution* is NMT that of the *Standard solution*; NMT 1.0%

Change to read:

• ORGANIC IMPURITIES

Buffer solution, Mobile phase, and System suitability solution: Prepare as directed in the Assay.

Standard solution: 0.001 mg/mL of [USP Prednisolone Sodium Phosphate RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Prednisolone Sodium Phosphate in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay, except for the *Run time*.

Run time: NLT 4 times the retention time of prednisolone sodium phosphate