

Status: Currently Official on 17-Feb-2025

Official Date: Official as of 01-May-2020

Document Type: USP Monographs

DocId: GUID-4A773BA8-BAEC-46E6-820E-E1225865DDC7_5_en-US

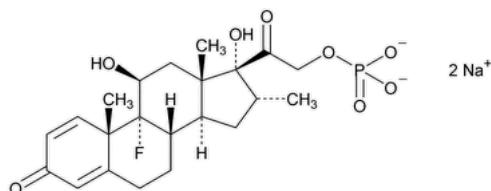
DOI: https://doi.org/10.31003/USPNF_M23450_05_01

DOI Ref: eg9o8

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Dexamethasone Sodium Phosphate


 $C_{22}H_{28}FNa_2O_8P$ 516.40

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonooxy)-, disodium salt, (11β,16α)-;

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-(dihydrogen phosphate) disodium salt CAS RN®: 2392-39-4; UNII: AI9376Y64P.

DEFINITION

Dexamethasone Sodium Phosphate contains NLT 97.0% and NMT 102.0% of dexamethasone sodium phosphate ($C_{22}H_{28}FNa_2O_8P$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** **▲ SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K ▲** (CN 1-MAY-2020): If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the Reference Standard separately in a minimum of alcohol, evaporate on a water bath to dryness, and repeat the test on the residues.
- **B.** **IDENTIFICATION TESTS—GENERAL, Phosphate (191):** The residue from its ignition meets the requirements.
- **C.** **IDENTIFICATION TESTS—GENERAL, Sodium (191):** The residue from its ignition meets the requirements.

ASSAY

PROCEDURE

Mobile phase: Mix 520 mL of water with 2 mL of phosphoric acid. Bring the temperature to 20°, and adjust with sodium hydroxide to a pH of 2.6. Mix this solution with 36 mL of tetrahydrofuran and 364 mL of methanol.

System suitability stock solution: 0.02 mg/mL each of [USP Dexamethasone Sodium Phosphate RS](#) and [USP Dexamethasone RS](#), prepared as follows. Dissolve 2 mg of each compound in 2 mL of tetrahydrofuran, and dilute with *Mobile phase* to 100 mL.

System suitability solution: 2 µg/mL each of [USP Dexamethasone Sodium Phosphate RS](#) and [USP Dexamethasone RS](#) in *Mobile phase* from the *System suitability stock solution*

Standard solution: 0.06 mg/mL of [USP Dexamethasone Sodium Phosphate RS](#) in *Mobile phase*

Sample solution: 0.06 mg/mL of Dexamethasone Sodium Phosphate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 7-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: 3 times the retention time of the dexamethasone sodium phosphate peak

System suitability

[NOTE—The relative retention times of the dexamethasone sodium phosphate and dexamethasone peaks are 1.0 and 2.0, respectively.]

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

Suitability requirements

Resolution: NLT 6.0 between dexamethasone sodium phosphate and dexamethasone peaks, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dexamethasone sodium phosphate ($C_{22}H_{28}FNa_2O_8P$) in the portion of Dexamethasone Sodium Phosphate 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 Dexamethasone Sodium Phosphate RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• LIMIT OF PHOSPHATE IONS

Solution A: 50 mg/mL of ammonium molybdate in 1 N sulfuric acid

Solution B: Dissolve 350 mg of *p*-methylaminophenol sulfate in 50 mL of water, add 20 g of sodium bisulfite, mix to dissolve, and dilute with water to 100 mL.

Standard stock solution: 0.14 mg/mL of dried monobasic potassium phosphate in water. This solution contains the equivalent of 0.10 mg/mL of phosphate (PO_4) ion.

Standard solution: In a 25-mL volumetric flask, mix 5.0 mL of *Standard stock solution*, 10 mL of water, and 5 mL of 2 N sulfuric acid. 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. Prepare concomitantly with the *Sample solution*.

Sample solution: In a 25-mL volumetric flask, dissolve 50 mg of Dexamethasone Sodium Phosphate in a mixture of 10 mL of water and 5 mL of 2 N sulfuric acid, 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.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: Visible

Analytical wavelength: 730 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The absorbance of the *Sample solution* is NMT that of the *Standard solution*. The limit is 1.0% of phosphate (PO_4).

• LIMIT OF ALCOHOL

Internal standard solution: 0.4 mg/mL of acetonitrile, prepared as follows. Dilute 5.0 mL of [USP Alcohol Determination–Acetonitrile RS](#) with water to 200.0 mL.

Standard stock solution: 0.20 mg/mL of alcohol, prepared as follows. Dilute 25.0 mL of [USP Alcohol Determination–Alcohol RS](#) with water to 2000.0 mL.

Standard solution: 0.08 mg/mL of alcohol, prepared as follows. Dilute 10.0 mL of the *Standard stock solution* and 5.0 mL of the *Internal standard solution* with water to 25.0 mL.

Sample solution: 5.0 mg/mL of Dexamethasone Sodium Phosphate, prepared as follows. Transfer 125 mg of Dexamethasone Sodium Phosphate to a 25-mL volumetric flask, add 5.0 mL of the *Internal standard solution*, and dilute with water to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary coated with 3-μm film of G43

Carrier gas: Hydrogen

Linear velocity: 36 cm/s

Split ratio: 2:1

Temperatures

Injection port: 210°

Detector: 280°

Column: See [Table 1](#).

Table 1