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Dexamethasone Sodium Phosphate Injection

DEFINITION

Dexamethasone Sodium Phosphate Injection is a sterile solution of Dexamethasone Sodium Phosphate in Water for Injection. It contains NLT 90.0% and NMT 115.0% of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$), present as the disodium salt.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Solution A: Mix 3.1 g of boric acid and 500 mL of water in a 1-L volumetric flask. Add 21 mL of 1 N sodium hydroxide and 10 mL of 0.1 M magnesium chloride, and dilute with water to volume.

Solution B: 1 mg/mL of alkaline phosphatase enzyme in *Solution A*

Standard solution: 300 µg/mL of USP Dexamethasone RS in methylene chloride

Sample solution: Pipet a volume of Injection, equivalent to 10 mg of dexamethasone phosphate, into a 100-mL volumetric flask, and dilute with water to volume. Pipet 5 mL of this solution into a 125-mL separator, and wash with two 10-mL portions of water-washed methylene chloride, discarding the washings. Transfer the solution to a glass-stoppered, 50-mL tube, and add 5 mL of *Solution B*. Allow to stand at 37° for 45 min, and extract with 25 mL of methylene chloride. Evaporate 15 mL of the methylene chloride extract on a steam bath to dryness, and dissolve the residue in 1 mL of methylene chloride.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture (20- × 20-cm plate)

Application volume: 5 µL

Developing solvent system: Chloroform, acetone, and water (50:50:1)

Spray reagent: Dilute sulfuric acid (1 in 2)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the spots to dry, and develop the chromatogram using the *Developing solvent system* in a tank completely lined with filter paper, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing tank, mark the solvent front, and allow the spots to dry. Spray the plate with *Spray reagent*, and heat at 105° until brown or black spots appear.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Mobile phase: 0.01 M monobasic potassium phosphate in a mixture of methanol and water (1:1)

Standard solution: 0.09 mg/mL of freshly prepared USP Dexamethasone Sodium Phosphate RS in *Mobile phase*

Sample solution: Nominally 0.08 mg/mL of dexamethasone phosphate from Injection, in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.6 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for dexamethasone phosphate is about 5 min.]

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}\blacktriangle_{(ERR\ 1\text{-}Feb\text{-}2023)}) \times 100$$

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 = nominal concentration of dexamethasone phosphate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of dexamethasone phosphate, 472.44

M_{r2} = molecular weight of dexamethasone sodium phosphate, 516.40

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 7.0–8.5
- **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 31.3 USP Endotoxin Units/mg of dexamethasone phosphate
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Dexamethasone RS
  USP Dexamethasone Sodium Phosphate RS

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

Topic/Question	Contact	Expert Committee
DEXAMETHASONE SODIUM PHOSPHATE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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