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Dexamethasone Sodium Phosphate Compounded Injection

DEFINITION

Dexamethasone Sodium Phosphate Compounded Injection 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. It contains no bacteriostat or other preservative.

Prepare Dexamethasone Sodium Phosphate Compounded Injection, 24 mg/mL, as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Dexamethasone phosphate (as Dexamethasone Sodium Phosphate)	240 mg (262.3 mg[a])
Sodium Citrate Dihydrate	100 mg
Sodium Bisulfite	10 mg
Sodium Hydroxide, 10% solution	To adjust the pH to 7.4
Sterile Water for Injection, a sufficient quantity to make	10 mL

[a] Calculate the amount of dexamethasone sodium phosphate based on the water content stated on the certificate of analysis.

Dissolve the *Dexamethasone Sodium Phosphate*, *Sodium Citrate Dihydrate*, and *Sodium Bisulfite* in about 8 mL of *Sterile Water for Injection*. Adjust with *Sodium Hydroxide 10% solution* to a pH of 7.4. Add sufficient *Sterile Water for Injection* to bring to final volume and mix well. Pass through a sterile filter of 0.22-µm pore size into sterile containers.

ASSAY

• **Procedure**

Solution A: Dissolve 6.8 g of monobasic potassium phosphate in 1000 mL of water and adjust with 6 N potassium hydroxide to a pH of 9.

Solution B: Acetonitrile and methanol (50:50)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
3.0	70	30
16.0	65	35
16.1	70	30
25.0	70	30

Diluent: Acetonitrile and water (25:75)

Standard solution: 0.12 mg/mL of dexamethasone phosphate prepared from USP Dexamethasone Sodium Phosphate RS in *Diluent*

Sample solution: Transfer 0.5 mL of the Injection to a 100-mL volumetric flask and dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for dexamethasone phosphate is about 15.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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:

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

r_U = peak response of dexamethasone phosphate from the *Sample solution*

r_S = peak response of dexamethasone phosphate from the *Standard solution*

C_S = concentration of dexamethasone phosphate in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 7.0–8.0
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 31.3 USP Endotoxin Units/mg of dexamethasone phosphate
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in light-resistant single-dose containers. Store at controlled room temperature.

Change to read:

- **Beyond-Use Date:** ▲In the absence of performing and completing a sterility and endotoxin test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations ⟨797⟩, 14.3 Establishing a BUD for a CSP* apply.▲ (CN 1-Nov-2023) After successful completion of sterility and endotoxin testing, NMT 90 days after the date on which it was compounded when stored at controlled room temperature.
- **Labeling:** Label it to indicate that it is a single-dose container and to state the *Beyond-Use Date*. Label to state that it should be protected from light.
- **USP Reference Standards ⟨11⟩**
  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 COMPOUNDED INJECTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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