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Add the following:

▲Dexamethasone Compounded Oral Suspension

DEFINITION

Dexamethasone Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$).

Prepare Dexamethasone Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Dexamethasone tablets,[a] equivalent to	100 mg of dexamethasone
Vehicle: Oral Mix[b] or Oral Mix SF,[b] a sufficient quantity to make	100 mL

[a] Dexamethasone 4-mg tablets, Pharmascience Inc., Montréal, Quebec.

[b] Medisca Pharmaceutique Inc., Montréal, Quebec.

Place the tablets in a suitable container and triturate to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a liquid that is pourable. Transfer the contents of the container, stepwise and quantitatively, to a calibrated bottle. Add a sufficient amount of *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 10 mM solution of ammonium formate adjusted with formic acid to a pH of 4

Solution B: Methanol, acetonitrile, and water (30:15:55)

Mobile phase: Methanol and *Solution A* (76:24)

Internal standard solution: 0.20 mg/mL of USP Naproxen RS in methanol

Standard solution: Transfer 10 mg of USP Dexamethasone RS to a 100-mL volumetric flask, add 10 mL of the *Internal standard solution*, and then dilute with *Solution B* to volume to obtain a solution containing 0.10 mg/mL of dexamethasone and 0.02 mg/mL of naproxen. Pass through a filter of 0.45-µm pore size.

Sample solution: Shake each bottle of Oral Suspension thoroughly. Transfer 10 mL of the Oral Suspension to a 100-mL volumetric flask, add 10 mL of the *Internal standard solution*, and dilute with methanol to volume. Mix well. Centrifuge at 5200 rpm for 5 min to obtain a solution containing 0.10 mg/mL of dexamethasone and 0.02 mg/mL of naproxen, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 238 nm

Columns

Guard: 3.9-mm × 2-cm; 5-µm packing L1

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

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention times for dexamethasone and naproxen are about 3.48 and 4.01 min, respectively.]

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 ($C_{22}H_{29}FO_5$) in the portion of Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of dexamethasone to the internal standard from the *Sample solution*

R_S = peak response ratio of dexamethasone to the internal standard from the *Standard solution*

C_S = concentration of USP Dexamethasone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **Labeling:** Label it to indicate that it is to be well shaken before use and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Dexamethasone RS

USP Naproxen RS▲ (USP 1-Dec-2021)

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

Topic/Question	Contact	Expert Committee
DEXAMETHASONE COMPOUNDED ORAL SUSPENSION	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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