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Dexamethasone Oral Solution

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

IDENTIFICATION
• **A.** The retention time of the dexamethasone peak from the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay.*

ASSAY
• **Procedure**

Mobile phase: Methanol and water (1:1)

Internal standard solution: 0.1 mg/mL of USP Prednisolone RS in methanol

System suitability stock solution: 0.6 mg/mL of USP Methylparaben RS and 0.075 mg/mL of USP Propylparaben RS in methanol

System suitability solution: 0.24 mg/mL of USP Methylparaben RS, 0.03 mg/mL of USP Propylparaben RS, and 0.01 mg/mL of USP Prednisolone RS prepared as follows. To an amount of *System suitability stock solution* equivalent to 40% of the final volume, add an amount of *Internal standard solution* equivalent to 10% of the final volume. Dilute with water to volume.

Standard stock solution: 0.2 mg/mL of USP Dexamethasone RS in *Mobile phase*

Standard solution: 0.02 mg/mL of USP Dexamethasone RS and 0.01 mg/mL of USP Prednisolone RS in *Mobile phase* prepared by diluting suitable volumes of *Standard stock solution* and *Internal standard solution*

Sample solution: Nominally equivalent to 0.02 mg/mL of dexamethasone from a volume of Oral Solution and 0.01 mg/mL of USP Prednisolone RS in *Mobile phase* from the *Internal standard solution*

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.4 mL/min

Injection volume: 10 µL

System suitability
[Note—The relative retention times for methylparaben, prednisolone, propylparaben, and dexamethasone are about 0.43, 0.71, 0.88, and 1.0, respectively.]

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

Suitability requirements

Resolution: NLT 2.0 between methylparaben and prednisolone; NLT 2.0 between propylparaben and prednisolone, *System suitability solution*

Tailing factor: NMT 2.0 for each peak, *System suitability solution* and *Standard solution*

Relative standard deviation: NMT 2.0% for the peak height ratio of dexamethasone to prednisolone, *Standard solution*

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 Solution taken:

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

R_U = peak height ratio of dexamethasone to prednisolone from the *Sample solution*

R_S = peak height ratio of dexamethasone to prednisolone 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%

OTHER COMPONENTS

• **Alcohol Determination,** *Method II* ⟨611⟩ (if present): 27.0%–33.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩**:** Meets the requirements for oral solution packaged in single-unit containers

• **Deliverable Volume** ⟨698⟩**:** Meets the requirements for oral solution packaged in multiple-unit containers

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.7–4.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.

• **Labeling:** Label concentrated Oral Solution to state that the term "**Concentrate**" is to appear apart from and immediately after the official title in prominent boldface type. Label concentrated Oral Solution also to indicate that it is to be diluted to appropriate strength with a suitable diluent prior to administration unless produced for dispensing with instructions for administration by a calibrated dropper or syringe.

• **USP Reference Standards** ⟨11⟩

USP Dexamethasone RS
USP Methylparaben RS
USP Prednisolone RS
USP Propylparaben RS

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

Topic/Question	Contact	Expert Committee
DEXAMETHASONE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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