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Desoximetasone Gel

DEFINITION

Desoximetasone Gel contains NLT 90.0% and NMT 110.0% of the labeled amount of desoximetasone ($C_{22}H_{29}FO_4$).

IDENTIFICATION

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

ASSAY

PROCEDURE

Mobile phase: Methanol, [glacial acetic acid](#), and [water](#) (65:1:35). Adjust the ratio, if necessary, so that the retention time of desoximetasone is about 8 min.

Diluent: 15 mg/mL of [calcium chloride](#) in methanol

Standard stock solution: 0.5 mg/mL of [USP Desoximetasone RS](#) in methanol

Standard solution: 0.025 mg/mL of [USP Desoximetasone RS](#) from the *Standard stock solution* in *Diluent*

Sample solution: Nominally 0.025 mg/mL of desoximetasone in *Diluent* prepared as follows. Transfer an adequate amount of Gel to a suitable volumetric flask. Add about 60% of the flask volume of *Diluent* and sonicate to disperse the Gel. Dilute with *Diluent* to volume and centrifuge. Use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of desoximetasone ($C_{22}H_{29}FO_4$) in the portion of Gel taken:

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

r_U = peak response of desoximetasone from the *Sample solution*

r_S = peak response of desoximetasone from the *Standard solution*

C_S = concentration of [USP Desoximetasone RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

ALCOHOL CONTENT

Sample solution: 50 mg/mL of Gel in methanol

Analysis: Determine the alcohol content of the *Sample solution* by proceeding as directed in [Alcohol Determination \(611\), Method II—Gas Chromatographic Method](#), using [isopropyl alcohol](#) as the internal standard and methanol in place of water as the solvent.

Acceptance criteria: 18.0%–24.0% (w/w)

PERFORMANCE TESTS

- **MINIMUM FILL (755):** Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes, at controlled room temperature.
- **USP REFERENCE STANDARDS (11).**
[USP Desoximetasone RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DESOXIMETASONE GEL	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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