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Desoximetasone Ointment

DEFINITION
Desoximetasone Ointment 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)

Diluent: Methanol and spectrophotometric acetonitrile saturated with *n*-heptane (1:1)

Standard stock solution: 0.4 mg/mL of USP Desoximetasone RS in methanol

Standard solution: 0.04 mg/mL of USP Desoximetasone RS from the *Standard stock solution* in *Diluent*

Sample solution: Nominally 0.04 mg/mL of desoximetasone in *Diluent* prepared as follows. Transfer an amount of Ointment nominally equivalent to 2 mg of desoximetasone to a 50-mL centrifuge tube. Add 20 mL of *n*-heptane that has been previously saturated with spectrophotometric acetonitrile, and heat gently with occasional shaking until the Ointment is completely dispersed. Allow to cool slightly, and extract with a 10-mL portion of spectrophotometric acetonitrile. Shake vigorously, centrifuge, remove the bottom layer of spectrophotometric acetonitrile with a syringe and needle, and transfer to a 50-mL volumetric flask. Using the same needle and syringe, extract the desoximetasone with successive 10- and 8-mL portions of spectrophotometric acetonitrile, combining all spectrophotometric acetonitrile layers in the 50-mL flask. Dilute with methanol nearly to volume, and allow the solution to reach room temperature. Dilute with methanol to volume.

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 5.0 between the desoximetasone and solvent peaks

Tailing factor: NMT 2.0

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 Ointment 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%

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 OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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