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Desoximetasone Cream

DEFINITION

Desoximetasone Cream is Desoximetasone in an emollient cream base. It 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)

Internal standard solution: 0.04 mg/mL of ethylparaben in methanol

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

Standard solution: 0.05 mg/mL of USP Desoximetasone RS and 0.01 mg/mL of ethylparaben from the *Standard stock solution* and *Internal standard solution*, respectively, in methanol

Sample solution: Transfer an amount of Cream, nominally equivalent to 2 mg of desoximetasone, to a 50-mL centrifuge tube, and add a few 3-mm glass beads. Add 10.0 mL of *Internal standard solution* and 30 mL of methanol. Tightly cap the centrifuge tube, and immerse it for 10 min in a bath maintained at 65°. Remove the tube from the bath, and immediately vortex at high speed for 30 s. Return the tube to the hot water bath for 5 min, remove it from the bath, and immediately vortex for 30 s. Repeat the procedure, then cool the tube in an ice-bath held at 10° until no further flocculent precipitation occurs. Centrifuge, and use the supernatant.

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*

[Note—The relative retention times for ethylparaben and desoximetasone are about 1 and 2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between desoximetasone and ethylparaben

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 Cream taken:

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

R_U = peak response ratio of desoximetasone to ethylparaben from the *Sample solution*

R_S = peak response ratio of desoximetasone to ethylparaben 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

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: Add 15 mL of boiling water to 3.5 g of Cream in a 50-mL centrifuge tube, cap the tube, shake vigorously until the Cream is uniformly dispersed, then place the tube in a steam bath until the water and oil layers separate completely. Cool and separate the layers.

Analysis: Determine the pH of the aqueous phase.

Acceptance criteria: 4.0–8.0

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 CREAM	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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