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Betamethasone Dipropionate Lotion

DEFINITION

Betamethasone Dipropionate Lotion contains an amount of betamethasone dipropionate ($C_{28}H_{37}FO_7$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$), in a suitable lotion base.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 150 µg/mL of USP Betamethasone Dipropionate RS in chloroform

Sample solution: Nominally 150 µg/mL of betamethasone dipropionate, prepared as follows. Transfer a portion of Lotion, equivalent to 0.6 mg of betamethasone dipropionate, to a 50-mL vial; add 10 mL of 0.1 N hydrochloric acid; then add 4 mL of chloroform. Disperse on a vortex mixer for about 1 min, shake vigorously for 10 min, and centrifuge at 2000 rpm for about 5 min. Transfer the chloroform layer to a suitable vial.

Chromatographic system

Application volume: 40 µL

Developing solvent system: Chloroform and acetone (7:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (1 in 2) such that the retention times for betamethasone dipropionate and beclomethasone dipropionate are 14 and 18 min, respectively. Degas by sonicating for 5–10 min. Do not leave the *Mobile phase* in the column overnight, but flush the system after use with water for 15 min, followed by methanol for 15 min.

Internal standard solution: 0.9 mg/mL of USP Beclomethasone Dipropionate RS in chloroform

Standard stock solution A: 0.6 mg/mL of USP Betamethasone Dipropionate RS in chloroform

Standard stock solution B: 0.3 mg/mL of betamethasone dipropionate and 0.45 mg/mL of beclomethasone dipropionate, prepared by combining 5.0 mL each of *Internal standard solution* and *Standard stock solution A*

Standard solution: To 10.0 mL of 0.1 N hydrochloric acid in a capped 5-mL centrifuge tube, add 4.0 mL of *Standard stock solution B*. Cap the tube, and shake vigorously for about 2 min, or disperse on a vortex mixer for about 1 min. Centrifuge at 2500 rpm for about 3 min. Transfer the chloroform phase to a suitable vial. Evaporate the chloroform under a stream of nitrogen at a slightly elevated temperature to dryness. Cool the vial to room temperature, add 4.0 mL of methanol, and swirl to dissolve the residue.

Sample solution: Nominally 0.23 mg/mL of betamethasone, prepared as follows. Transfer a portion of Lotion, equivalent to 1.2 mg of betamethasone dipropionate (0.93 mg of betamethasone), into a capped 50-mL centrifuge tube. Add 10.0 mL of 0.1 N hydrochloric acid, shake to disperse, then add 2.0 mL of *Internal standard solution* and 2.0 mL of chloroform. Cap, and shake vigorously for about 2 min, or disperse on a vortex mixer for about 1 min. Centrifuge at 2500 rpm for about 3 min. Transfer the chloroform phase to a suitable vial. Evaporate the chloroform under a stream of nitrogen at a slightly elevated temperature to dryness. Cool the vial to room temperature, add 4.0 mL of methanol, and swirl to dissolve the residue.

Chromatographic system

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

Mode: LC

Detector: UV 254 or 240 nm

Column: 4-mm × 30-cm; packing L1

Injection volume: 5–25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Peak area ratios: The lowest and highest peak area ratios of three successive injections agree within 2.0%.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$) in the portion of Lotion taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

R_U = peak height ratio of betamethasone dipropionate to the internal standard from the *Sample solution*

R_S = peak height ratio of betamethasone dipropionate to the internal standard from the *Standard solution*

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

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

M_{r1} = molecular weight of betamethasone, 392.46

M_{r2} = molecular weight of betamethasone dipropionate, 504.59

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at 25°, excursions permitted between 15° and 30°. Protect from light and freezing.

• **USP Reference Standards ⟨11⟩**

USP Beclomethasone Dipropionate RS

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

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

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