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Betamethasone Dipropionate Cream

DEFINITION

Betamethasone Dipropionate Cream 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 cream base.

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).

Standard solution: 150 µg/mL of [USP Betamethasone Dipropionate RS](#) in chloroform

Sample solution: Nominally equivalent to 150 µg/mL of betamethasone dipropionate, prepared as follows. Transfer 1.5 g of Cream to a glass-stoppered, 50-mL centrifuge tube. Add 15 mL of a methanol–hydrochloric acid solution prepared by mixing 1 volume of dilute hydrochloric acid (1 in 120) with 4 volumes of methanol. Shake to obtain a homogeneous mixture. Add 30 mL of solvent hexane, mix for 10 min, and centrifuge. Using a syringe, transfer the lower aqueous phase to a second centrifuge tube, and add 20 mL of water. Extract this aqueous mixture with chloroform by shaking, centrifuging, and removing the lower, chloroform phase with a syringe. Evaporate the chloroform on a steam bath with the aid of a stream of nitrogen to dryness, cool, and dissolve the residue in chloroform.

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.

Diluent: Acetic acid in methanol (1 in 1000)

Internal standard solution: 0.45 mg/mL of [USP Beclomethasone Dipropionate RS](#) in *Diluent*

Standard stock solution: 0.2 mg/mL of [USP Betamethasone Dipropionate RS](#) in *Diluent*

Standard solution: 0.133 mg/mL of [USP Betamethasone Dipropionate RS](#) and 0.15 mg/mL of [USP Beclomethasone Dipropionate RS](#) prepared by combining 10.0 mL of the *Standard stock solution* and 5.0 mL of the *Internal standard solution*

Sample solution: Nominally equivalent to 0.1 mg/mL of betamethasone, prepared as follows. Transfer a portion of Cream, equivalent to 2 mg of betamethasone dipropionate (1.6 mg of betamethasone), into a capped 50-mL centrifuge tube. Add 5.0 mL of *Internal standard solution* and 10.0 mL of *Diluent*. Heat in a water bath at 60°, shaking intermittently, until the Cream melts. Remove from the bath, and shake vigorously until the Cream has resolidified. Repeat the heating and shaking. Freeze in an ice–methanol bath for 15 min, and centrifuge at 2500 rpm for 5 min. Use the supernatant.

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 Cream taken:

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%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or tight containers. Store at 25°, excursions permitted between 15° and 30°. Protect from freezing.
- [USP REFERENCE STANDARDS \(11\)](#)
 - [USP Beclomethasone Dipropionate RS](#)
 - [USP Betamethasone Dipropionate RS](#)

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

Topic/Question	Contact	Expert Committee
BETAMETHASONE DIPROPIONATE CREAM	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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