Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-780CCBCF-62F0-41F1-946E-1677C246DDED_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9020_01_01
DOI Ref: pdz6h

Betamethasone Dipropionate Ointment

DEFINITION

Betamethasone Dipropionate Ointment 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 ointment 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 1.5 g of Ointment to a glass-stoppered, 50-mL centrifuge tube. Add 15 mL of 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 and alcohol (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 Ointment, 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 70°, shaking intermittently, until the sample melts. Remove from the bath, and shake vigorously until the Ointment has solidified. 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 Ointment 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 from 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°, with 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 OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 29(5)

Current DocID: GUID-780CCBCF-62F0-41F1-946E-1677C246DDED_1_en-US

DOI: https://doi.org/10.31003/USPNF_M9020_01_01

DOI ref: pdz6h