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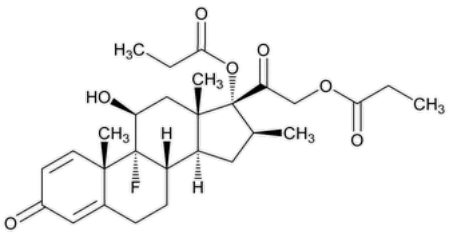
Betamethasone Dipropionate



$C_{28}H_{37}FO_7$ 504.59

Pregna-1,4-diene-3,20-dione, 9-fluoro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-, (11β,16β);

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate CAS RN®: 5593-20-4; UNII: 826Y60901U.

DEFINITION

Betamethasone Dipropionate contains NLT 97.0% and NMT 103.0% of betamethasone dipropionate ($C_{28}H_{37}FO_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)

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

Sample solution: 1 mg/mL, in chloroform

Chromatographic system

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

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 *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 methanol (1 in 1000)

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

Standard stock solution: 0.6 mg/mL of USP Betamethasone Dipropionate RS in *Diluent*

Standard solution: 0.3 mg/mL of USP Betamethasone Dipropionate RS and 0.45 mg/mL of USP Beclomethasone Dipropionate RS, prepared by combining 5.0 mL each of the *Internal standard solution* and the *Standard stock solution*

Sample stock solution: 0.6 mg/mL of Betamethasone Dipropionate in *Diluent*

Sample solution: 0.3 mg/mL of Betamethasone Dipropionate, prepared by combining 5.0 mL each of the *Internal standard solution* and the *Sample stock solution*

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 betamethasone dipropionate ($C_{28}H_{37}FO_7$) in the portion of Betamethasone Dipropionate taken:

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

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 = concentration of Betamethasone Dipropionate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%, using a platinum crucible
- **Organic Impurities**

Mobile phase: Acetonitrile and water (65:35)

System suitability solution: 0.05 mg/mL of USP Betamethasone Dipropionate RS and 0.05 mg/mL of USP Betamethasone Valerate RS in *Mobile phase*

Sample solution: 0.3 mg/mL of Betamethasone Dipropionate in *Mobile phase*. Shake until dissolved.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 4.0 between betamethasone valerate and betamethasone dipropionate

Column efficiency: NLT 8000 theoretical plates

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Betamethasone Dipropionate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of the responses for all the peaks

Acceptance criteria

Individual impurities: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- **Optical Rotation, *Specific Rotation*⟨781S⟩**

Sample solution: 10 mg/mL, in dioxane

Acceptance criteria: +63° to +70°

- **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at 25°, excursions permitted between 15° and 30°.
- **USP Reference Standards ⟨11⟩**

USP Beclomethasone Dipropionate RS
USP Betamethasone Dipropionate RS
USP Betamethasone Valerate RS

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(3)

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