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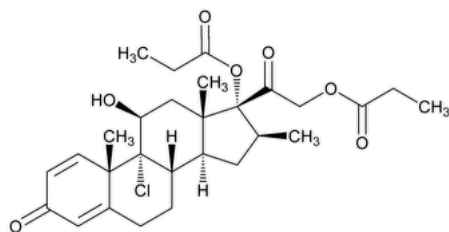
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Beclomethasone Dipropionate


 $C_{28}H_{37}ClO_7 \cdot H_2O$ 539.07

 $C_{28}H_{37}ClO_7$ 521.04
Pregna-1,4-diene-3,20-dione, 9-chloro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-, (11 β ,16 β)-;9-Chloro-11 β ,17,21-trihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17,21-dipropionate CAS RN®: 5534-09-8.

DEFINITION

Beclomethasone Dipropionate is anhydrous or contains one molecule of water of hydration. It contains NLT 97.0% and NMT 103.0% of beclomethasone dipropionate ($C_{28}H_{37}ClO_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-MAY-2020)

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and water (60:40) such that the retention times for beclomethasone dipropionate and testosterone propionate are approximately 6 and 10 min, respectively

Internal standard solution: 1.2 mg/mL of [USP Testosterone Propionate RS](#) in methanol

Standard stock solution: 1.4 mg/mL of [USP Beclomethasone Dipropionate RS](#) in methanol

Standard solution: 0.7 mg/mL of [USP Beclomethasone Dipropionate RS](#) and 0.6 mg/mL of [USP Testosterone Propionate RS](#) prepared as follows. Transfer 4.0 mL of *Standard stock solution* to a suitable vial, and add 4.0 mL of *Internal standard solution*.

Sample stock solution: 1.4 mg/mL of Beclomethasone Dipropionate in methanol

Sample solution: 0.7 mg/mL of Beclomethasone Dipropionate and 0.6 mg/mL of [USP Testosterone Propionate RS](#) prepared as follows.

Transfer 4.0 mL of *Sample stock solution* to a suitable vial, and add 4.0 mL of *Internal standard solution*.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Injection volume: 5–25 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of beclomethasone dipropionate ($C_{28}H_{37}ClO_7$) in the portion of Beclomethasone Dipropionate taken:

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

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

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

C_s = concentration of [USP Beclomethasone Dipropionate RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#).

Sample solution: 10 mg/mL in dioxane

Acceptance criteria: +88° to +94°

- [LOSS ON DRYING \(731\)](#).

Analysis: Dry a sample at 105° for 3 h.

Acceptance criteria: NMT 0.5% for the anhydrous form; 2.8%–3.8% for the monohydrate form

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Beclomethasone Dipropionate RS](#)

[USP Testosterone Propionate RS](#)

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

Topic/Question	Contact	Expert Committee
BECLOMETHASONE DIPROPIONATE	Documentary Standards Support	SM52020 Small Molecules 5
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(2)

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