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Beclomethasone Dipropionate Compounded Oral Solution

DEFINITION

Beclomethasone Dipropionate Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of beclomethasone dipropionate ($C_{28}H_{37}ClO_7$).

Prepare Beclomethasone Dipropionate Compounded Oral Solution 0.5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Beclomethasone Dipropionate powder	50 mg
Corn Oil, *NF*, a sufficient quantity to make	100 mL

Pour the *Beclomethasone Dipropionate powder* into a suitable container. Wet the powder with a small amount of *Corn Oil* and triturate to make a smooth paste. Add the *Corn Oil* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the *Corn Oil*. Add sufficient *Corn Oil* to bring to final volume. Place on a shaker until dissolved. [Note—May take up to 24 h to dissolve.]

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (65:35)

Standard stock solution: 0.5 mg/mL of beclomethasone dipropionate prepared from USP Beclomethasone Dipropionate RS in ethanol. Sonicate and mix well.

Standard solution: 0.02 mg/mL of beclomethasone diproprionate prepared from *Standard stock solution* and ethanol

Sample solution: Transfer 1.0 mL of Oral Solution to a 25-mL volumetric flask, add approximately 20 mL of ethanol, vortex for 30 s, and warm under running water until dissolved. Dilute with ethanol to volume.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 240 nm

Column: 2.0-mm × 10-cm; 2.5-µm packing L1

Column temperature: 35°

Flow rate: 0.35 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for beclomethasone dipropionate is about 3.2 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of beclomethasone dipropionate ($C_{28}H_{37}ClO_7$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of beclomethasone dipropionate from the *Sample solution*

r_S = peak response of beclomethasone dipropionate from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant, plastic containers. Store at controlled room temperature.
- **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature.
- **Labeling:** Label it to be well-shaken before use, and to state the *Beyond-Use Date*.
- **USP Reference Standards** ⟨11⟩
  USP Beclomethasone Dipropionate RS

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

Topic/Question	Contact	Expert Committee
BECLOMETHASONE DIPROPIONATE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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