

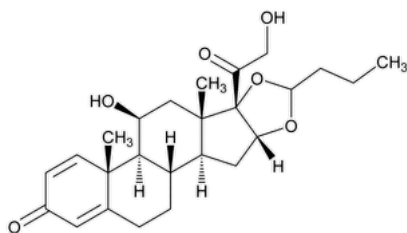
Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Jul-2021
 Document Type: USP Monographs
 DocId: GUID-D0084C97-1F78-41D5-B757-1DDC46CACB2E_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M10458_04_01
 DOI Ref: b5vgm

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Budesonide

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$C_{25}H_{34}O_6$ 430.53

Pregna-1,4-diene-3,20-dione, 16,17-butyldienebis(oxy)-11,21-dihydroxy-, [11b,16a(R)], and 16a,17-[(S)-Butyldienebis(oxy)]-11b,21-dihydroxypregna-1,4-diene-3,20-dione;

(RS)-11b,16a,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde CAS RN®: 51333-22-3; UNII: Q3OKS62Q6X.

S epimer CAS RN®: 51372-28-2; UNII: 168L5HT37P.

R epimer CAS RN®: 51372-29-3; UNII: 2HI1006KPH.

DEFINITION

Budesonide is a mixture of two epimeric forms, epimer A (C-22S) and epimer B (C-22R). It contains NLT 40.0% and NMT 51.0% of epimer A, and the sum of both epimers is NLT 98.0% and NMT 102.0% of budesonide ($C_{25}H_{34}O_6$), calculated on the dried basis.

[NOTE—Protect all solutions containing Budesonide from light.]

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K
- **B. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Ultraviolet-Visible Spectroscopy*: 197U

Sample solution: 25 µg/mL

Medium: [Methanol](#)

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Buffer: 0.5 mL of [glacial acetic acid](#) in 1 L of [water](#). Adjust with [potassium hydroxide](#) to a pH of 3.9.

Mobile phase: [Acetonitrile](#) and *Buffer* (45:55)

Standard solution: 0.06 mg/mL of [USP Budesonide RS](#) prepared as follows. Transfer [USP Budesonide RS](#) to a suitable volumetric flask, dissolve in [acetonitrile](#) equivalent to 30% of the flask volume, and dilute with [water](#) to volume.

Sample solution: 0.06 mg/mL of Budesonide prepared as follows. Transfer Budesonide to a suitable volumetric flask, dissolve in [acetonitrile](#) equivalent to 30% of the flask volume, and dilute with [water](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 3-µm packing [L1](#)

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention time for epimer B is 0.96 with respect to epimer A.]

Suitability requirements

Resolution: NLT 1.2 between the two budesonide epimer peaks

Relative standard deviation: NMT 1.0%, for the sum of the peak areas of the two budesonide epimers

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of budesonide epimer A (C₂₅H₃₄O₆) in the portion of Budesonide taken:

$$\text{Result} = [r_{UA} / (r_{UA} + r_{UB})] \times 100$$

r_{UA} = peak area of epimer A from the *Sample solution*

r_{UB} = peak area of epimer B from the *Sample solution*

Calculate the percentage of budesonide (C₂₅H₃₄O₆) in the portion of Budesonide taken:

$$\text{Result} = [(r_{UA} + r_{UB}) / (r_{SA} + r_{SB})] \times (C_S / C_U) \times 100$$

r_{UA} = peak area of epimer A from the *Sample solution*

r_{UB} = peak area of epimer B from the *Sample solution*

r_{SA} = peak area of epimer A from the *Standard solution*

r_{SB} = peak area of epimer B from the *Standard solution*

C_S = concentration of [USP Budesonide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Budesonide in the *Sample solution* (mg/mL)

Acceptance criteria

Epimer A: 40.0%–51.0%

Both epimers: 98.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Solution A: 0.5 mL of [glacial acetic acid](#) in 1 L of [water](#). Adjust with [potassium hydroxide](#) to a pH of 3.9.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
5	75	25
35	68	32
42	59	41
59	25	75
60	75	25
70	75	25

Diluent: [Acetonitrile](#) and [water](#) (3:7)

System suitability stock solution A: 0.3 mg/mL of [USP Budesonide Related Compound E RS](#) in [acetonitrile](#)

System suitability stock solution B: 0.3 mg/mL of [USP Budesonide Related Compound G RS](#) in [acetonitrile](#)

System suitability stock solution C: 0.3 mg/mL of [USP Budesonide Related Compound L RS](#) in [acetonitrile](#)

System suitability solution: 0.6 mg/mL of [USP Budesonide RS](#) and 3 µg/mL each of [USP Budesonide Related Compound E RS](#), [USP Budesonide Related Compound G RS](#), and [USP Budesonide Related Compound L RS](#) in *Diluent* prepared as follows. Transfer [USP Budesonide RS](#) to a suitable volumetric flask and add suitable quantities of *System suitability stock solution A*, *System suitability stock solution B*, and *System suitability stock solution C*. Dilute with [acetonitrile](#) equivalent to 30% of the final volume and dilute with [water](#) to volume.