

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2020
 Document Type: USP Monographs
 DocId: GUID-3D774F8D-C554-44B5-BE09-A7FB6B0B43A3_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M10462_02_01
 DOI Ref: ha7nm

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Add the following:

▲Budesonide Nasal Spray

DEFINITION

Budesonide Nasal Spray is an aqueous buffered suspension of Budesonide, supplied in a form suitable for nasal administration and contains suitable preservatives. It contains NLT 90.0% and NMT 110.0% of the labeled amount of budesonide ($C_{25}H_{34}O_6$).

IDENTIFICATION

- **A.** The retention time of the budesonide peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the budesonide peak of the *Sample solution* exhibits a maximum and minimum at the same wavelengths as those of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Mobile phase: [Acetonitrile](#) and [water](#) (70:30)

[NOTE—Use low-actinic glassware for preparation of the *Standard solution* and *Sample solution*.]

Standard solution: 0.05 mg/mL of [USP Budesonide RS](#) in [acetonitrile](#)

Sample solution: Nominally 0.05 mg/mL of budesonide in [acetonitrile](#) prepared as follows. Prepare a composite by mixing NLT 5 containers of Nasal Spray in a suitable container. Weigh a quantity of the composite solution into a suitable volumetric flask. Dilute with [acetonitrile](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 245 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 50 μL

Run time: NLT 2 times the retention time of budesonide

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of budesonide ($C_{25}H_{34}O_6$) in the portion of Nasal Spray taken:

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

r_U = peak response of budesonide from the *Sample solution*

r_S = peak response of budesonide from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• CONTENT OF POTASSIUM SORBATE

Perform this test if potassium sorbate is a component in the Nasal Spray.

Buffer: 1.4 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to pH 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60)

Standard solution: 0.04 mg/mL of [USP Potassium Sorbate RS](#) in [water](#)

Sample solution: Nominally 0.04 mg/mL of potassium sorbate in [water](#) prepared as follows. Prepare a composite by mixing NLT 5 containers of Nasal Spray in a suitable container. Transfer 1.0 mL of the well-mixed composite solution to a 25-mL volumetric flask containing 10 mL of [water](#). Add 5 drops of 0.5 N [hydrochloric acid](#). Dilute with [water](#) to volume. Centrifuge for about 10 min at about 3600 rpm, and use the clear solution.

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 4 times the retention time of potassium sorbate

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of potassium sorbate ($C_6H_7KO_2$) in the portion of Nasal Spray taken:

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

r_U = peak response of potassium sorbate from the *Sample solution*

r_S = peak response of potassium sorbate from the *Standard solution*

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

C_U = nominal concentration of potassium sorbate in the *Sample solution* (mg/mL)

Acceptance criteria: 50.0%–110.0%

• CONTENT OF EDETATE DISODIUM

Perform this test if edetate disodium is a component in the Nasal Spray.

Buffer: 17 g/L of [tetrabutylammonium hydrogen sulfate](#) in [water](#). Adjust with 2 M [ammonium acetate](#) to a pH of 4.4.

Solution A: [Methanol](#), *Buffer*, and [water](#) (12:20:68)

Solution B: [Methanol](#), *Buffer*, and [water](#) (70:7:23)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
10	100	0
11	0	100
20	0	100

Diluent: Dissolve 250 mg of [cupric sulfate](#) in 400 mL of [water](#). Add 100 mL of *Buffer*. Mix well and filter.

Standard stock solution: 0.25 mg/mL of [USP Edetate Disodium RS](#) in [water](#)

Standard solution: 0.05 mg/mL of [USP Edetate Disodium RS](#) in *Diluent* from *Standard stock solution*

Sample solution: Nominally 0.05 mg/mL of edetate disodium in *Diluent* prepared as follows. Prepare a composite by mixing NLT 5 containers of Nasal Spray in a suitable container. Transfer 5.0 mL of the composite solution to a 10-mL volumetric flask. Add 0.5 mL of 0.5 N [hydrochloric acid](#). Dilute with *Diluent* to volume. Centrifuge for about 10 min at about 3600 rpm, and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm