

Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2023
Document Type: USP Monographs
DocId: GUID-8FC9762B-E4CA-4945-B0AB-488C4FB954A0_3_en-US
DOI: https://doi.org/10.31003/USPNF_M1218_03_01
DOI Ref: v4vpy

© 2025 USPC
Do not distribute

Albuterol Tablets

DEFINITION

Albuterol Tablets contain an amount of albuterol sulfate $[(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4]$ equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of albuterol $(C_{13}H_{21}NO_3)$.

IDENTIFICATION

Change to read:

- **A.** ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2023)

Change to read:

- **B.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2023)

ASSAY

Change to read:

• PROCEDURE

Solution A: 10 mL/L of [glacial acetic acid](#) in [water](#)

Solution B: 1.13 g of [sodium 1-hexanesulfonate](#) in 1200 mL of [water](#). Add 12 mL of [glacial acetic acid](#).

Diluent: [Methanol](#) and [water](#) (40:60)

Mobile phase: [Methanol](#) and *Solution B* (40:60)

Standard stock solution: 0.12 mg/mL of [USP Albuterol Sulfate RS](#) prepared as follows. ▲Transfer a suitable amount of [USP Albuterol Sulfate RS](#) to a suitable volumetric flask. Add 60% of the flask volume of *Solution A* and sonicate for about 5 min. Dilute with [methanol](#) to volume.▲ (USP 1-May-2023)

Standard solution: 0.03 mg/mL of [USP Albuterol Sulfate RS](#)▲ (USP 1-May-2023) from *Standard stock solution*▲ in *Diluent*▲ (USP 1-May-2023)

Sample solution: Nominally 0.025 mg/mL of albuterol prepared as follows. Transfer a number of whole Tablets, equivalent to 50 mg of albuterol, to a suitable volumetric flask. Add 60% of the flask volume of *Solution A*, shake by mechanical means for ▲about▲ (USP 1-May-2023) 45 min, and sonicate for ▲about▲ (USP 1-May-2023) 10 min. Allow to cool to room temperature and dilute with [methanol](#) to volume. Pass through a suitable filter of 0.45-μm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2023)

Column: 4.6-mm × 15-cm; ▲5-μm▲ (USP 1-May-2023) packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 25 μL

▲**Run time:** NLT 2.5 times the retention time of albuterol▲ (USP 1-May-2023)

System suitability

Sample: *Standard solution*

Suitability requirements

▲ (USP 1-May-2023)

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of albuterol $(C_{13}H_{21}NO_3)$ in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times M \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response [▲]of albuterol [▲](USP 1-May-2023) from the *Sample solution*

r_S = peak response [▲]of albuterol [▲](USP 1-May-2023) from the *Standard solution*

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

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

M = number of moles of albuterol per mole of albuterol sulfate, 2

M_{r1} = molecular weight of albuterol, 239.31

M_{r2} = molecular weight of albuterol sulfate, 576.70

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#) [▲](USP 1-May-2023)

Medium: [Water](#) 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Diluent, Mobile phase, and Standard stock solution: Prepare as directed in the Assay.

Standard solution: 0.03 mg/mL of [USP Albuterol Sulfate RS](#) in *Diluent*, from *Standard stock solution*. If necessary, dilute with *Diluent* to a concentration corresponding to the *Sample solution*.

Sample solution: Pass a portion of the solution under test through a [▲]suitable [▲](USP 1-May-2023) filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

Column: 4.6-mm × 15-cm; [▲]5-μm [▲](USP 1-May-2023) packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 100 μL

[▲]Run time: NLT 2.5 times the retention time of albuterol [▲](USP 1-May-2023)

System suitability

Sample: *Standard solution*

Suitability requirements

[▲](USP 1-May-2023)

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of albuterol ($C_{13}H_{21}NO_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times M \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

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

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

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

V = volume of *Medium*, 500 mL

M = number of moles of albuterol per mole of albuterol sulfate, 2

M_{r1} = molecular weight of albuterol, 239.31

M_{r2} = molecular weight of albuterol sulfate, 576.70

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of albuterol ($C_{13}H_{21}NO_3$) is dissolved.