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Albuterol Extended-Release Tablets

DEFINITION

Albuterol Extended-Release Tablets contain albuterol sulfate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of albuterol ($C_{13}H_{21}NO_3$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

- **B.** ▲ **SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Ultraviolet-Visible Spectroscopy*: **197U** ▲ (CN 1-MAY-2020)

Standard solution: 80 µg/mL of albuterol from [USP Albuterol Sulfate RS](#) in methanol

Sample solution: 80 µg/mL of albuterol in methanol, prepared as follows. Transfer a suitable number of Tablets to a volumetric flask, and dilute with methanol to volume. Stir for 30 min, and centrifuge.

Wavelength range: 210–350 nm

Cell path: 0.2 cm

Acceptance criteria: The *Sample solution* exhibits maxima and minima only at the same wavelengths as the *Standard solution*.

ASSAY

• PROCEDURE

Buffer: 0.65 g/L of sodium 1-octane sulfonate and 21.7 g/L of ammonium acetate in water

Mobile phase: Glacial acetic acid, 2-propanol, methanol, and *Buffer* (4:3:1:92)

Diluent: 10 mL/L of triethylamine in water

Standard stock solution: 0.2 mg/mL of [USP Albuterol Sulfate RS](#) in *Diluent*

Standard solution: 0.02 mg/mL of [USP Albuterol Sulfate RS](#) in *Diluent*, from the *Standard stock solution*. Transfer an aliquot of the *Standard stock solution* to a suitable volumetric flask, and add 4% of the flask volume of methanol. Allow to cool to room temperature, and dilute with *Diluent* to volume.

Sample solution: Nominally 0.016 mg/mL of albuterol, prepared as follows. Transfer Tablets (NLT 10) to a suitable volumetric flask, add 10% of the flask volume of methanol, and sonicate for 30 min with regular swirling. Add 60% of the flask volume of *Diluent*, and sonicate for 30 min with swirling. Stir for 60 min, allow the solution to cool to room temperature, and dilute with *Diluent* to volume. Centrifuge a portion of this solution at 2500 rpm for 15 min. Transfer 10 mL of the supernatant into a 50-mL volumetric flask, add 1 mL of methanol, cool to room temperature, and dilute with *Diluent* to volume. Pass the solution through a 1-µm glass fiber or equivalent filter, and discard the first 3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 40 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 2000 theoretical plates

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 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 from the *Sample solution*

r_S = peak response 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 = 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

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm, with helix sinker

Time: 1, 2, 4, and 9 h

Buffer, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay, except to use an *Injection volume* of 50 μ L.

Standard stock solution: 0.2 mg/mL of albuterol, using [USP Albuterol Sulfate RS](#), in *Medium*

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of (L/1000) mg/mL of albuterol, where L is the label claim in mg/Tablet of albuterol.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_i) of albuterol ($C_{13}H_{21}NO_3$) in the sample withdrawn from the vessel at each time point (i):

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of albuterol in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of albuterol ($C_{13}H_{21}NO_3$) released at each time point (i):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + [C_1 \times V_S]\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{[C_3 \times (V - (2 \times V_S))] + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$\text{Result}_4 = \{[C_4 \times (V - (3 \times V_S))] + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

C_i = concentration of albuterol in the portion of sample withdrawn at time point i (mg/mL)

V = volume of the *Medium* (900 mL)

L = label claim (mg/Tablet)

V_S = volume of the *Sample solution* withdrawn from the *Medium* (mL)

Tolerances: See [Table 1](#).

Table 1

Time point (i)	Time (h)	Amount released (%)
1	1	25–45
2	2	45–65



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