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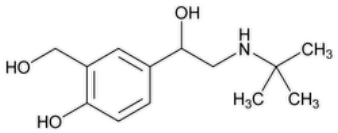
Albuterol



$C_{13}H_{21}NO_3$ 239.31

1,3-Benzenedimethanol, α^1-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-;

α^1-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α'-diol CAS RN®: 18559-94-9; UNII: QF8SVZ843E.

DEFINITION

Albuterol contains NLT 98.5% and NMT 101.0% of albuterol ($C_{13}H_{21}NO_3$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Change to read:

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020)

Sample solution: 80 µg/mL in 0.1 N hydrochloric acid

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Sample solution: 8 mg/mL of Albuterol in glacial acetic acid

Analysis: To 50 mL of the *Sample solution* add 2 drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 23.93 mg of $C_{13}H_{21}NO_3$.

Acceptance criteria: 98.5%–101.0% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Standard solution: 0.10 mg/mL of USP Albuterol RS in methanol

Sample solution: 20 mg/mL of Albuterol in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 10 µL

Developing solvent system: Methyl isobutyl ketone, isopropyl alcohol, ethyl acetate, ammonium hydroxide, and water (50:45:35:3:18)

Visualization: Iodine vapor

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter, applying aliquots of the *Standard solution* and the *Sample solution*. Develop in the *Developing solvent system* until the solvent front has moved three-fourths the length of the plate. Remove the plate from the developing chamber, air-dry, and expose it to iodine vapor.

Acceptance criteria: Any spot, other than the principal spot, obtained from the *Sample solution* is not greater in size and intensity than the spot produced by the *Standard solution* (0.5%), and the sum of the impurities is not greater than 2.0%.

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers.
- **USP Reference Standards** ⟨11⟩
  USP Albuterol RS

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

Topic/Question	Contact	Expert Committee
ALBUTEROL	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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