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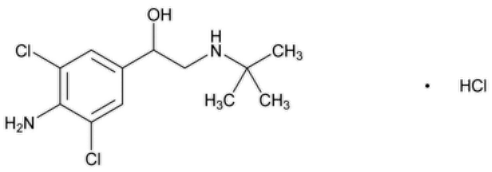
Clenbuterol Hydrochloride



$C_{12}H_{18}Cl_2N_2O \cdot HCl$ 313.65

Ethanol, 1-(4-amino-3,5-dichlorophenyl)-2-(*tert*-butylamino), hydrochloride;

4-Amino-α-[(*tert*-butylamino)methyl]-3,5-dichlorobenzyl alcohol, hydrochloride CAS RN®: 21898-19-1; UNII: GOR5747GWU.

DEFINITION

Clenbuterol Hydrochloride contains NLT 98.0% and NMT 102.0% of $C_{12}H_{18}Cl_2N_2O \cdot HCl$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

• **B.** Identification Tests—General, *Chloride* ⟨191⟩: Meets the requirements

ASSAY

• **Procedure**

Sample solution: Dissolve 0.25 g in 50 mL of alcohol, and add 5.0 mL of 0.01 N hydrochloric acid.

Analysis: Titrate with 0.1 N sodium hydroxide VS, determining the endpoint potentiometrically. Read the volume added between the two points of inflection. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N sodium hydroxide is equivalent to 31.37 mg of $C_{12}H_{18}Cl_2N_2O \cdot HCl$.

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

Inorganic Impurities

• Residue on Ignition ⟨281⟩: NMT 0.1%, from 1–2 g

Organic Impurities

• **Procedure**

Buffer: Dissolve 3.0 g of sodium 1-decanesulfonate and 5.0 g of monobasic potassium phosphate in 900 mL of water, adjust with dilute phosphoric acid (1 in 10) to a pH of 3.0, and dilute with water to 1000 mL.

Mobile phase: Acetonitrile, methanol, and *Buffer* (2:2:6)

System suitability solution: 0.2 mg/mL each of USP Clenbuterol Related Compound B RS and Clenbuterol Hydrochloride in *Mobile phase*

Sample solution 1: 2.0 mg/mL of Clenbuterol Hydrochloride in *Mobile phase*

Sample solution 2: 2.0 µg/mL of Clenbuterol Hydrochloride in *Mobile phase*, from *Sample solution 1*

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 215 nm

Column: 4.0-mm × 12.5-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.5 mL/min

Injection size: 5 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 4.0 between clenbuterol related compound B and clenbuterol

Relative standard deviation: NMT 2.0% for the clenbuterol peak

Analysis

Samples: *Sample solution 1* and *Sample solution 2*

Calculate the percentage of impurities in the portion of $C_{12}H_{18}Cl_2N_2O \cdot HCl$ taken:

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

r_U = peak response of each impurity from *Sample solution 1*

r_S = peak response of clenbuterol from *Sample solution 2*

C_S = concentration of Clenbuterol Hydrochloride in *Sample solution 2* (mg/mL)

C_U = concentration of Clenbuterol Hydrochloride in *Sample solution 1* (mg/mL)

Acceptance criteria

Individual impurities: 0.1%

Total impurities: NMT 0.2%

[NOTE—The reporting level for impurities is 0.05%.]

SPECIFIC TESTS

- **OPTICAL ROTATION,** *Specific Rotation* ⟨781S⟩

  Sample: 30 mg/mL in water, filter as necessary

  Acceptance criteria: −10° to +10° at 20°
- **pH** ⟨791⟩**:** 5.0–7.0

  Sample: 50 mg/mL in carbon dioxide-free water
- **WATER DETERMINATION,** *Method I* ⟨921⟩**:** NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light. Store at room temperature.
- **LABELING:** Label it to indicate that it is for veterinary use only.
- **USP REFERENCE STANDARDS** ⟨11⟩

  USP Clenbuterol Hydrochloride RS

  USP Clenbuterol Related Compound B RS

  1-(4-Amino-3,5-dichlorophenyl)-2-*tert*-butyl-aminoethanone hydrochloride.

  $C_{12}H_{16}Cl_2N_2O \cdot HCl$ 311.64

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

Topic/Question	Contact	Expert Committee
CLENBUTEROL HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(5)

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