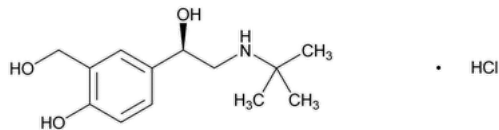


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Levalbuterol Hydrochloride

Change to read:



$C_{13}H_{21}NO_3 \cdot HCl$ 275.77

▲Phenol, 4-[2-(*tert*-butylamino)-1-hydroxyethyl]-2-(hydroxymethyl), hydrochloride, (*R*)-;
(*R*)-α-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α'-diol hydrochloride;▲ (IRA 1-Nov-2022)
(*R*)-α¹-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α'-diol hydrochloride CAS RN[®]: 50293-90-8; ▲UNII: WDQ1526QJM.▲ (IRA 1-Nov-2022)

DEFINITION

Levalbuterol Hydrochloride contains NLT 98.0% and NMT 102.0% of levalbuterol hydrochloride ($C_{13}H_{21}NO_3 \cdot HCl$), calculated on the anhydrous basis.

IDENTIFICATION

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K

Change to read:

• **B.** The retention time of the major peak of the ▲*Identification sample solution*▲ (IRA 1-Nov-2022) corresponds to that of the levalbuterol peak of the *System suitability solution*, as obtained in the test for *Limit of S-Albuterol*.

ASSAY

Change to read:

• **PROCEDURE**

Solution A: Dilute 1 mL of [phosphoric acid](#) with [water](#) to 1 L.
Solution B: [Acetonitrile](#), [methanol](#), and [water](#) (35:35:30). To each liter of the solution add 1 mL of [phosphoric acid](#).
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	91.5	8.5
15	91.5	8.5
15.01	0	100
20	0	100
20.01	91.5	8.5
30	91.5	8.5

Diluent: *Solution A*
Standard solution: 100 µg/mL of [USP Levalbuterol Hydrochloride RS](#) in *Diluent*
Sample solution: 100 µg/mL of Levalbuterol Hydrochloride in *Diluent*
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.3

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of levalbuterol hydrochloride ($C_{13}H_{21}NO_3 \cdot HCl$) in the portion of Levalbuterol Hydrochloride taken:

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

r_U = peak response ▲ of levalbuterol ▲ (IRA 1-Nov-2022) from the *Sample solution*

r_S = peak response ▲ of levalbuterol ▲ (IRA 1-Nov-2022) from the *Standard solution*

C_S = concentration of [USP Levalbuterol Hydrochloride RS](#) in the *Standard solution* (μg/mL)

C_U = concentration of the *Sample solution* (μg/mL)

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- LIMIT OF **S-ALBUTEROL**

Mobile phase: [Acetonitrile](#) and [methanol](#) (50:50). To each liter of the solution add 3 mL of [acetic acid](#) and 1 mL of [triethylamine](#).

Diluent: *Mobile phase*

System suitability solution: 0.10 mg/mL of [USP Levalbuterol Hydrochloride RS](#) and 0.04 mg/mL of [USP Albuterol RS](#) in *Diluent*

Sample solution: 0.8 mg/mL of Levalbuterol Hydrochloride in *Diluent*

▲ Identification sample solution: ▲ (IRA 1-Nov-2022) 0.1 mg/mL ▲ of Levalbuterol Hydrochloride ▲ (IRA 1-Nov-2022) from the *Sample solution* ▲ in *Diluent* ▲ (IRA 1-Nov-2022)

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L63](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 1.5 times the retention time of levalbuterol

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for levalbuterol and (S)-albuterol are 1.0 and 1.16, respectively.]

Suitability requirements

Resolution: NLT 2.0 between levalbuterol and (S)-albuterol

Tailing factor: NMT 2.2 for levalbuterol and (S)-albuterol

Analysis

Sample: *Sample solution* ▲ (IRA 1-Nov-2022)

Calculate the percentage of (S)-albuterol in the portion of Levalbuterol Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of (S)-albuterol from the *Sample solution*

r_T = sum of the peak responses for levalbuterol and (S)-albuterol from the *Sample solution*

Acceptance criteria: NMT 0.2% of (S)-albuterol

Change to read:

- ORGANIC IMPURITIES