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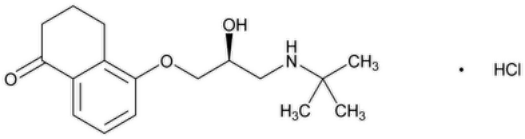
Levobunolol Hydrochloride



$C_{17}H_{25}NO_3 \cdot HCl$ 327.85

1(2*H*)-Naphthalenone, 5-[3-[(1,1-dimethylethyl)amino]-2-hydroxypropoxy]-3,4-dihydro-, hydrochloride, (−)-*(S)*;

(−)-5-[3-(*tert*-Butylamino)-2-hydroxypropoxy]-3,4-dihydro-1(2*H*)-naphthalenone hydrochloride CAS RN®: 27912-14-7; UNII: O90S49LDHH.

DEFINITION

Levobunolol Hydrochloride contains NLT 98.0% and NMT 102.0% of levobunolol hydrochloride ($C_{17}H_{25}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

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

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

ASSAY

• **Procedure**

Solution A: 5 mM sodium 1-heptanesulfonate in methanol

Solution B: 5 mM sodium 1-heptanesulfonate in water

Mobile phase: *Solution A*, 0.5 M sulfuric acid, and *Solution B* (53:1:47)

Standard solution: 100 µg/mL of USP Levobunolol Hydrochloride RS in *Mobile phase*

Sample solution: 100 µg/mL of Levobunolol Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 223 nm

Column: 3.9 mm × 25 cm; 10-µm packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of levobunolol hydrochloride ($C_{17}H_{25}NO_3 \cdot HCl$) in the portion of Levobunolol Hydrochloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Levobunolol Hydrochloride RS in the *Standard solution* (µg/mL)

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

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

IMPURITIES

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

• **Organic Impurities**

Solution A, Solution B, and **Mobile phase:** Proceed as directed in the *Assay*.

System suitability solution: 50 µg/mL each of USP Levobunolol Hydrochloride RS and USP Atenolol RS in *Mobile phase*

Standard solution: 5 µg/mL of USP Levobunolol Hydrochloride RS in *Mobile phase*

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

Chromatographic system: Proceed as directed in the *Assay* using *Mobile phase*.

Run time: 3 times the retention time of levobunolol

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 8 between levobunolol and atenolol peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Levobunolol Hydrochloride taken:

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

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

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

C_S = concentration of USP Levobunolol Hydrochloride RS in the *Standard solution* (µg/mL)

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

Acceptance criteria

Individual impurity: NMT 0.5%

Total impurities: NMT 1%

SPECIFIC TESTS

• **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 30 mg/mL in methanol

Acceptance criteria: −19° to −20°

• **pH ⟨791⟩**

Sample: 50 mg/mL

Acceptance criteria: 4.5–6.5

• **Loss on Drying ⟨731⟩**

Sample: 1 g

Analysis: Dry under vacuum over phosphorus pentoxide at 110° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Protect from light. Store at room temperature.

• **USP Reference Standards ⟨11⟩**

USP Atenolol RS

USP Levobunolol Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
LEVOBUNOLOL HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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