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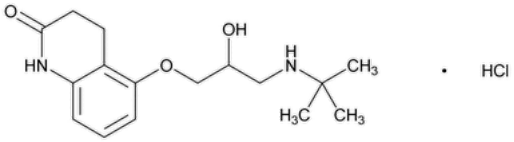
Carteolol Hydrochloride



$C_{16}H_{24}N_2O_3 \cdot HCl$ 328.83

2(1*H*)-Quinolinone, 5-[3-[(1,1-dimethylethyl)amino]-2-hydroxypropoxy]-3,4-dihydro-, monohydrochloride;

5-[3-(*tert*-Butylamino)-2-hydroxypropoxy]-3,4-dihydrocarbo styril monohydrochloride CAS RN®: 51781-21-6; UNII: 4797W6I0T4.

DEFINITION

Carteolol Hydrochloride contains NLT 98.0% and NMT 101.5% of carteolol hydrochloride ($C_{16}H_{24}N_2O_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K ▲or 197A▲ (USP 1-May-2023)

Delete the following:

▲• **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*▲** (USP 1-May-2023)

Add the following:

▲• **B.** The retention time of major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2023)

Change to read:

• **C. ▲Identification Tests—General ⟨191⟩ Chemical Identification Tests, Chloride▲** (USP 1-May-2023)

Sample solution: 20 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

Change to read:

• **Procedure**

▲Solution A: 2.82 g/L of sodium 1-hexanesulfonate in water

Mobile phase: Acetonitrile, methanol, and *Solution A* (20:1:79)

Standard solution: 0.1 mg/mL of USP Carteolol Hydrochloride RS in *Mobile phase*

Sample solution: 0.1 mg/mL of Carteolol Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 252 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 3.3 times the retention time of carteolol

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.5%▲ (USP 1-May-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carteolol hydrochloride ($C_{16}H_{24}N_2O_3 \cdot HCl$) in the portion of Carteolol Hydrochloride taken:

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

r_U = peak response of carteolol from the *Sample solution*

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

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

C_U = concentration of Carteolol Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.5% on the dried basis

IMPURITIES

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

Delete the following:

▲• **Arsenic ⟨211⟩, *Procedures, Method II*** ▲(USP 1-May-2023)

Change to read:

• **Organic Impurities**

▲**Solution A, Mobile phase,** and **Chromatographic system:** Proceed as directed in the *Assay*.

System suitability solution: 2 mg/mL of USP Carteolol Hydrochloride RS, 0.002 mg/mL of USP Carteolol Related Compound F RS, and 0.004 mg/mL of USP Dehydrocarteolol Hydrochloride RS in *Mobile phase*

Sensitivity solution: 0.001 mg/mL of USP Carteolol Hydrochloride RS in *Mobile phase*

Standard solution: 0.002 mg/mL of USP Carteolol Hydrochloride RS and 0.004 mg/mL of USP Dehydrocarteolol Hydrochloride RS in *Mobile phase*

Sample solution: 2 mg/mL of Carteolol Hydrochloride in *Mobile phase*

System suitability

Samples: *System suitability solution*, *Sensitivity solution*, and *Standard solution*

[Note—The relative retention times for carteolol related compound F, dehydrocarteolol, and carteolol are about 0.77, 0.83, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between carteolol related compound F and dehydrocarteolol; NLT 2.0 between dehydrocarteolol and carteolol, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0% for carteolol and dehydrocarteolol, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dehydrocarteolol hydrochloride in the portion of Carteolol Hydrochloride taken:

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

r_U = peak response of dehydrocarteolol from the *Sample solution*

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

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

C_U = concentration of Carteolol Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Carteolol Hydrochloride taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

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

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

C_U = concentration of Carteolol Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*. The reporting threshold is 0.05%.

Table 1

	Relative Retention	Acceptance Criteria

[a] 5-[3-(*tert*-Butylamino)-2-hydroxypropoxy]quinolin-2(1*H*)-one.

Name	Retention Time	Criteria, NMT (%)
Dehydrocarteolol[a]	0.83	0.2
Carteolol	1.0	—
Any unspecified impurity	—	0.10
Total impurities	—	0.5▲ (USP 1-May-2023)

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 10 mg/mL

Acceptance criteria: 5.0–6.0

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Carteolol Hydrochloride RS

▲ USP Carteolol Related Compound F RS

5-(2-Hydroxy-3-methoxypropoxy)-3,4-dihydroquinolin-2(1*H*)-one.

$C_{13}H_{17}NO_4$ 251.28

USP Dehydrocarteolol Hydrochloride RS

5-[3-(*tert*-Butylamino)-2-hydroxypropoxy]quinolin-2(1*H*)-one hydrochloride.

$C_{16}H_{22}N_2O_3 \cdot HCl$ 326.82▲ (USP 1-May-2023)

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

Topic/Question	Contact	Expert Committee
CARTEOLOL HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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