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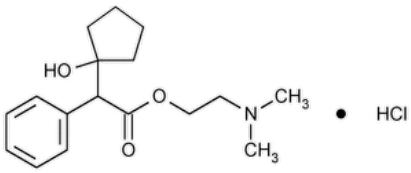
Cyclopentolate Hydrochloride



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

Benzeneacetic acid, α-(1-hydroxycyclopentyl)-, 2-(dimethylamino)ethyl ester, hydrochloride, (±)-;

2-(Dimethylamino)ethyl (±)-1-hydroxy-α-phenylcyclopentaneacetate hydrochloride CAS RN®: 5870-29-1; UNII: 736I6971TE.

DEFINITION

Cyclopentolate Hydrochloride contains NLT 98.0% and NMT 102.0% of cyclopentolate 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*: 197K**▲ (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 ⟨191⟩, *Chemical Identification Tests, Chloride***

Sample solution: 2 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Buffer solution: Dissolve 660 mg of *dibasic ammonium phosphate* in 1000 mL of water. Adjust with *phosphoric acid* to a pH of 3.0 ± 0.1.

Mobile phase: *Acetonitrile* and *Buffer solution* (7:3)

Standard solution: 0.1 mg/mL of USP Cyclopentolate Hydrochloride RS in *water*

Sample solution: 0.1 mg/mL of Cyclopentolate Hydrochloride in *water*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 5-µm packing *L15*

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cyclopentolate hydrochloride ($C_{17}H_{25}NO_3 \cdot HCl$) in the portion of Cyclopentolate 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 Cyclopentolate Hydrochloride RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.05%

• **Organic Impurities**

Buffer solution, Mobile phase, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*, except for the *Run time*.

Run time: NLT twice the retention time of cyclopentolate

Analysis

Sample: *Sample solution*

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

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

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

r_T = sum of the responses of all of the peaks, excluding the solvent peak, from the *Sample solution*

Acceptance criteria

Individual impurity: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: 10 mg/mL

Acceptance criteria: 4.5–5.5

• **Loss on Drying ⟨731⟩**

Sample: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store in a cold place.

• **USP Reference Standards ⟨11⟩**

USP Cyclopentolate Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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