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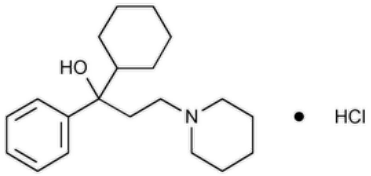
Trihexyphenidyl Hydrochloride



$C_{20}H_{31}NO \cdot HCl$ 337.93

1-Piperidinepropanol, α-cyclohexyl-α-phenyl-, hydrochloride, (±)-;

(±)-α-Cyclohexyl-α-phenyl-1-piperidinepropanol hydrochloride CAS RN®: 52-49-3; UNII: AO61G82577.

DEFINITION

Trihexyphenidyl Hydrochloride contains NLT 98.0% and NMT 102.0% of trihexyphenidyl hydrochloride ($C_{20}H_{31}NO \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)
- **B.** **Identification Tests—General, *Chloride* ⟨191⟩**
- **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Solution A: Add 0.2 mL of triethylamine in 200 mL of water and mix. Adjust with phosphoric acid to a pH of 4.0.

Mobile phase: Acetonitrile and *Solution A* (75:25)

Standard solution: 0.2 mg/mL of USP Trihexyphenidyl Hydrochloride RS in acetonitrile

Sample solution: 0.2 mg/mL of Trihexyphenidyl Hydrochloride in acetonitrile

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: 3 times the retention time of trihexyphenidyl

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1300 theoretical plates

Tailing factor: NMT 3.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trihexyphenidyl hydrochloride ($C_{20}H_{31}NO \cdot HCl$) in the portion of Trihexyphenidyl 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 Trihexyphenidyl Hydrochloride RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

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

• **Organic Impurities**

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

Standard stock solution: 0.02 mg/mL of USP Trihexyphenidyl Hydrochloride RS in *Mobile phase*

System suitability solution: 0.01 mg/mL of USP Trihexyphenidyl Related Compound A RS in *Standard stock solution*

Standard solution: 0.002 mg/mL of USP Trihexyphenidyl Hydrochloride RS from *Standard stock solution* in *Mobile phase*

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

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between trihexyphenidyl and trihexyphenidyl related compound A, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Signal-to-noise ratio: NLT 50, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

r_S = peak response of trihexyphenidyl hydrochloride from the *Standard solution*

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

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

Acceptance criteria: See *Table 1*. Disregard any peaks below 0.02%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Trihexyphenidyl related compound A	0.47	0.5
Trihexyphenidyl	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	0.5

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 0.5%

- **pH** ⟨791⟩

Sample solution: 10 mg/mL in water

Acceptance criteria: 5.2–6.2

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

USP Trihexyphenidyl Hydrochloride RS

USP Trihexyphenidyl Related Compound A RS

1-Phenyl-3-(piperidin-1-yl)propan-1-one hydrochloride.

$C_{14}H_{19}NO \cdot HCl$ 253.77

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

Topic/Question	Contact	Expert Committee
TRIHEXYPHENIDYL HYDROCHLORIDE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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