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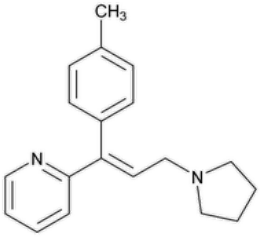
Triprolidine Hydrochloride



· HCl · H_2O

$C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ 332.87
$C_{19}H_{22}N_2 \cdot HCl$ 314.86

Pyridine, 2-[1-(4-methylphenyl)-3-(1-pyrrolidinyl)-1-propenyl]-, monohydrochloride, monohydrate, (*E*)-;
(*E*)-2-[3-(1-Pyrrolidinyl)-1-*p*-tolylpropenyl]pyridine monohydrochloride monohydrate CAS RN®: 6138-79-0; UNII: YAN7R5L890.
Anhydrous CAS RN®: 550-70-9; UNII: NG7A104R3J.

DEFINITION

Triprolidine Hydrochloride contains NLT 98.0% and NMT 102.0% of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl$), calculated on the anhydrous 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, *Chloride* ⟨191⟩

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, formic acid, and water (200:1:800) prepared as follows. Mix 200 mL of acetonitrile with 800 mL of water, add 1 mL of formic acid, and sonicate.

Diluent: Acetonitrile and water (20:80)

System suitability solution: 0.01 mg/mL each of USP Triprolidine Hydrochloride RS and USP Triprolidine Hydrochloride *Z*-Isomer RS in *Diluent*

Standard solution: 0.1 mg/mL of USP Triprolidine Hydrochloride RS in *Diluent* prepared as follows. Transfer a suitable amount of USP Triprolidine Hydrochloride RS to a suitable volumetric flask and dissolve, by sonication, in about 60% of the flask volume of *Diluent*. Dilute with *Diluent* to volume.

Sample solution: 0.1 mg/mL of Triprolidine Hydrochloride in *Diluent* prepared as follows. Transfer a suitable amount of Triprolidine Hydrochloride to a suitable volumetric flask and dissolve, by sonication, in about 60% of the flask volume of *Diluent*. Dilute with *Diluent* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25.0-cm; 5-µm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: 20 min

System suitability

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

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

Suitability requirements

Resolution: NLT 5.0 between triprolidine hydrochloride and triprolidine hydrochloride *Z*-isomer, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl$) in the portion of Triprolidine 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 Triprolidine Hydrochloride RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
- **ORGANIC IMPURITIES**

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

Standard solution: 10 µg/mL each of USP Triprolidine Hydrochloride RS and USP Triprolidine Hydrochloride *Z*-Isomer RS in *Diluent*

Sample solution: 0.5 mg/mL of Triprolidine Hydrochloride in *Diluent* prepared as follows. Transfer a suitable amount of Triprolidine Hydrochloride to a suitable volumetric flask and dissolve, by sonication, in about 60% of the flask volume of *Diluent*. Dilute with *Diluent* to volume.

System suitability

Sample: *Standard solution*

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

Suitability requirements

Resolution: NLT 5.0 between triprolidine hydrochloride and triprolidine hydrochloride *Z*-isomer

Relative standard deviation: NMT 1.8% for each peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of triprolidine hydrochloride *Z*-isomer in the portion of Triprolidine Hydrochloride taken:

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

r_U = peak response of triprolidine hydrochloride *Z*-isomer from the *Sample solution*

r_S = peak response of triprolidine hydrochloride *Z*-isomer from the *Standard solution*

C_S = concentration of USP Triprolidine Hydrochloride *Z*-Isomer RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Triprolidine 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 triprolidine hydrochloride from the *Standard solution*

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

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Triprolidine	1.0	—
Triprolidine hydrochloride *Z*-isomer	1.5	2.0
Any individual unspecified impurity	—	0.10
Total impurities	—	3.0

SPECIFIC TESTS

• **Water Determination, *Method I* ⟨921⟩:** 4.0%–6.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Triprolidine Hydrochloride RS

USP Triprolidine Hydrochloride *Z*-Isomer RS

(*Z*)-2-[3-(1-Pyrrolidinyl)-1-*p*-tolylpropenyl]pyridine monohydrochloride.

$C_{19}H_{22}N_2 \cdot HCl$ 314.85

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

Topic/Question	Contact	Expert Committee
TRIPROLIDINE HYDROCHLORIDE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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