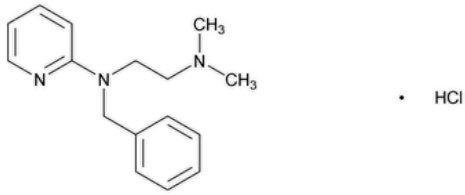
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-613A8EF7-757A-49E8-B7A0-7CFD841921B6_2_en-US
DOI: https://doi.org/10.31003/USPNF_M86170_02_01
DOI Ref: 9gfw0

Tripelennamine Hydrochloride



$C_{16}H_{21}N_3 \cdot HCl$ 291.82

1,2-Ethanediamine, *N*,*N*-dimethyl-*N*'-(phenylmethyl)-*N*'-2-pyridinyl-, monohydrochloride;

2-[Benzyl[2-(dimethylamino)ethyl]amino]pyridine monohydrochloride CAS RN®: 154-69-8; UNII: FWV8GJ56ZN.

DEFINITION

Tripelennamine Hydrochloride contains NLT 98.0% and NMT 102.0% of tripelennamine hydrochloride ($C_{16}H_{21}N_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 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*:** Meets the requirements

ASSAY

- **Procedure**

Solution A: 29 mM sodium 1-octanesulfonate solution

Mobile phase: Methanol, *N*,*N*-dimethyloctylamine, and *Solution A* (530:1:430), prepared as follows. Transfer 530 mL of methanol to a suitable container, add 1.0 mL of *N*,*N*-dimethyloctylamine, and mix thoroughly. Add 430 mL of *Solution A*, mix, and adjust with phosphoric acid to a pH of 3.0.

Benzaldehyde stock solution: Transfer 1.0 mL of benzaldehyde to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Benzaldehyde solution: Transfer 5.0 mL of the *Benzaldehyde stock solution* to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

System suitability stock solution: 0.5 mg/mL of 2-benzylaminopyridine in *Mobile phase* prepared as follows. Transfer 50 mg of 2-benzylaminopyridine to a 100-mL volumetric flask. Add 10 mL of methanol, sonicate to dissolve, and dilute with *Mobile phase* to volume.

System suitability solution: Transfer 5.0 mL of the *System suitability stock solution* to a 100-mL volumetric flask. Add 5.0 mL of *Benzaldehyde solution*, and dilute with *Mobile phase* to volume.

Standard solution: 0.5 mg/mL of USP Tripelennamine Hydrochloride RS in *Mobile phase*

Sample solution: 0.5 mg/mL of Tripelennamine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Column temperature: 35°

[Note—New columns are conditioned with *Mobile phase* overnight before the initial use, and may be reconditioned, as necessary, thereafter.]

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—The relative retention times for benzaldehyde and 2-benzylaminopyridine are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.5 between benzaldehyde and 2-benzylaminopyridine, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tripelennamine hydrochloride ($C_{16}H_{21}N_3 \cdot HCl$) in the portion of Tripelennamine 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 Tripelennamine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Tripelennamine 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**

Solution A, Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Tripelennamine 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 all the peak responses from the *Sample solution*

Acceptance criteria

Each individual impurity: NMT 0.1%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• **LOSS ON DRYING ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Tripelennamine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TRIPELENNAMINE 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:
Pharmacopeial Forum: Volume No. PF 42(2)

Current DocID: GUID-613A8EF7-757A-49E8-B7A0-7CFD841921B6_2_en-US
DOI: https://doi.org/10.31003/USPNF_M86170_02_01
DOI ref: 9gfw0