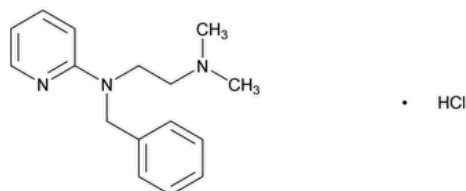


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-613A8EF7-757A-49E8-B7A0-7CFD841921B6_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M86170_02_01
 DOI Ref: 9gfw0

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Tripeleppamine 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

Tripeleppamine Hydrochloride contains NLT 98.0% and NMT 102.0% of tripeleppamine 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 Tripeleppamine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Tripeleppamine 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 tripeleonnamine hydrochloride ($C_{16}H_{21}N_3 \cdot HCl$) in the portion of Tripeleonnamine 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 Tripeleonnamine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Tripeleonnamine 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 Tripeleonnamine 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 Tripeleonnamine Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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