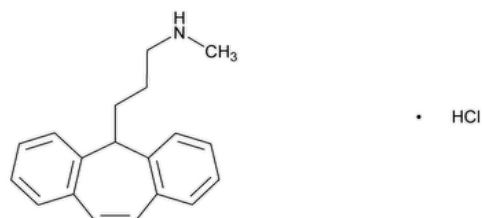


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Protriptyline Hydrochloride



$C_{19}H_{21}N \cdot HCl$ 299.84

5H-Dibenzo[a,d]cycloheptene-5-propanamine, N-methyl-, hydrochloride;

N-Methyl-5H-dibenzo[a,d]cycloheptene-5-propylamine hydrochloride CAS RN[®]: 1225-55-4; UNII: 44665V0008.

DEFINITION

Protriptyline Hydrochloride contains NLT 99.0% and NMT 101.0% of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** ▲197K or ▲(IRA 1-Jan-2025) 197M
- **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:** 197U

Analytical wavelength: 292 nm

Sample solution: 10 µg/mL of Protriptyline Hydrochloride in 0.1 N methanolic hydrochloric acid

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

Change to read:

- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride:** ▲Meets the requirements of the test for amine hydrochlorides ▲

(IRA 1-Jan-2025)

Change to read:

- **D. ▲SPECTROSCOPIC IDENTIFICATION TESTS (197), X-Ray Powder Diffraction:** 197XR ▲(IRA 1-Jan-2025)

Acceptance criteria: Its X-ray diffraction pattern conforms to that of [USP Protriptyline Hydrochloride RS](#).

ASSAY

Change to read:

• PROCEDURE

Sample: 700 mg of Protriptyline Hydrochloride

Blank: 30 mL of [glacial acetic acid](#)

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [0.1 N perchloric acid VS](#)

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 125-mL conical flask, and dissolve in 30 mL of [glacial acetic acid](#). Add [crystal violet TS](#) and 10 mL of [mercuric acetate TS](#), and titrate with *Titrant* to a green endpoint. Perform a blank determination, and make any necessary correction.

▲ Calculate the percentage of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$) in the *Sample* taken:

$$\text{Result} = \{[(V_s - V_b) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 299.84 mg/mEq

W = *Sample* weight (mg)▲ (IRA 1-Jan-2025)

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: 10 mg/mL of Protriptyline Hydrochloride in [water](#)

Acceptance criteria: 5.0–6.5

- [Loss on Drying \(731\)](#)

Analysis: Dry at a pressure not exceeding 5 mm of mercury at 60° to constant weight.

Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Protriptyline Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
PROTRIPTYLINE 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](#)

Most Recently Appeared In:

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