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Protriptyline Hydrochloride Tablets

DEFINITION
Protriptyline Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$).

IDENTIFICATION
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Buffer: Dissolve 11 g of monobasic sodium phosphate and 1.9 g of sodium 1-hexanesulfonate in 900 mL of water. Dilute with water to 1 L and adjust with phosphoric acid to a pH of 2.9.

Solution A: Acetonitrile and *Buffer* (17:83)

Solution B: Acetonitrile and *Buffer* (50:50)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	0	100
20	0	100
25	100	0
30	100	0

Diluent: Mix 200 mL of alcohol and 40 mL of 2.5 N hydrochloric acid, and dilute with water to 1000 mL.

Standard solution: 200 µg/mL of USP Protriptyline Hydrochloride RS in *Diluent*

Sample solution: Nominally 200 µg/mL of protriptyline hydrochloride prepared as follows. Transfer NLT 5 Tablets to an appropriate volumetric flask. Add *Diluent* to about 80% of the flask volume, sonicate, and swirl as necessary to dissolve. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size and discard the first 8 mL of the filtrate.

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

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$) in the portion of Tablets 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 Protriptyline Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of protriptyline hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: USP Protriptyline Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute the filtrate with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution*.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 290 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor for the *Sample solution*, if needed

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of protriptyline hydrochloride ($C_{19}H_{21}N \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.2 µg/mL of USP Protriptyline Hydrochloride RS in *Diluent*

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of each unspecified degradation product from the *Sample solution*

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

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

C_U = nominal concentration of protriptyline hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: Disregard any impurity peaks less than 0.05%.

Any individual, unspecified degradation product: NMT 0.2%

Total degradation products: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.
- **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 TABLETS	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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