

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* ($\mu\text{g/mL}$)

C_U = nominal concentration of protriptyline hydrochloride in the *Sample solution* ($\mu\text{g/mL}$)

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 $\mu\text{g/mL}$ 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*