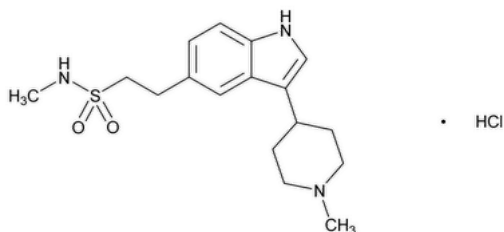


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Naratriptan Hydrochloride



$C_{17}H_{25}N_3O_2S \cdot HCl$ 371.93

1*H*-Indole-5-ethanesulfonamide, *N*-methyl-3-(1-methyl-4-piperidyl)-, monohydrochloride;

N-Methyl-3-(1-methyl-4-piperidyl)indole-5-ethanesulfonamide monohydrochloride CAS RN[®]: 143388-64-1; UNII: 10X8X4P12Z.

Change to read:

DEFINITION

Naratriptan Hydrochloride contains NLT 98.0% and NMT 101.0% of naratriptan hydrochloride ($C_{17}H_{25}N_3O_2S \cdot HCl$), calculated on the anhydrous and solvent-free basis.

▲ (USP 1-May-2021)

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197M
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Delete the following:

- ▲ • **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chloride](#): It meets the requirements of test C. ▲ (USP 1-May-2021)

Add the following:

- ▲ • **C. CHLORIDE**

[CAUTION—This test evolves chlorine gas.]

Sample: Mix the solid under test with an equal weight of [manganese dioxide](#) and moisten with [sulfuric acid](#).

Analysis: Gently heat the *Sample*, while exposing moistened [starch iodide paper](#) to the evolving gas.

Acceptance criteria: A gas evolves producing a blue color on the paper. ▲ (USP 1-May-2021)

ASSAY

Change to read:

- **PROCEDURE**

▲ [NOTE—Store the *System suitability solution*, *Standard solution*, and *Sample solution* in a cool place, protected from light.] ▲ (USP 1-May-2021)

Solution A: Dilute 0.6 mL of [phosphoric acid](#) with [water](#) to 900 mL. Adjust with [triethylamine](#) to a pH of 2.5.

Mobile phase: [Isopropyl alcohol](#) and *Solution A* (1:9)

System suitability solution: 0.7 mg/mL of [USP Naratriptan Resolution Mixture RS](#) in *Mobile phase*

Standard solution: 0.11 mg/mL of [USP Naratriptan Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.11 mg/mL of Naratriptan Hydrochloride in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 282 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L11](#)

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

▲ **Run time:** NLT 2 times the retention time of naratriptan ▲ (USP 1-May-2021)

System suitability

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

[NOTE—The relative retention times for naratriptan related compound A, naratriptan, and naratriptan related compound B are 0.9, 1.0, and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the naratriptan related compound A and naratriptan peaks; NLT 1.5 between the naratriptan and naratriptan related compound B peaks, *System suitability solution*

Relative standard deviation: ▲NMT 0.73%,▲ (USP 1-May-2021) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of naratriptan hydrochloride ($C_{17}H_{25}N_3O_2S \cdot HCl$) in the portion of Naratriptan 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 Naratriptan Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Naratriptan Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.0% on the anhydrous and solvent-free basis

IMPURITIES

Change to read:

• **ORGANIC IMPURITIES**

▲[NOTE—Store the *System suitability solution* and *Sample solution* in a cool place, protected from light.]▲ (USP 1-MAY-2021)

Buffer: 5.75 g/L of [monobasic ammonium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.00 ± 0.05 .

Solution A: [Acetonitrile](#) and *Buffer* (3:97)

Solution B: [Acetonitrile](#) and *Buffer* (20:80)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35	0	100
40	0	100
41	100	0
51	100	0

System suitability solution: 0.11 mg/mL of [USP Naratriptan Resolution Mixture RS](#) in [water](#)

Sample solution: 0.11 mg/mL of Naratriptan Hydrochloride in [water](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 4-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Sample: *System suitability solution*

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between naratriptan and naratriptan related compound B

Analysis

Sample: *Sample solution*