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Naratriptan Tablets

DEFINITION

Naratriptan Tablets contain an amount of Naratriptan Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of naratriptan ($C_{17}H_{25}N_3O_2S$).

IDENTIFICATION

Delete the following:

▲ A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Diluent: Methylene chloride and methanol (1:1)

Standard solution: 1.0 mg/mL of [USP Naratriptan Hydrochloride RS](#) prepared as follows. Transfer 5.5 mg of [USP Naratriptan Hydrochloride RS](#) to a 25-mL flask, add 1 mL of water and gently shake. Add 4.5 mL of *Diluent*, and shake for 5 min. Centrifuge at 3000 rpm for 10 min, and pass through a suitable filter of a 0.45-μm pore size.

Sample solution: Transfer a number of Tablets equivalent to 5 mg of naratriptan to a 25-mL flask, add 1.0 mL of water to wet the tablets, and gently shake to remove the Tablet film coating. Add 4.5 mL of *Diluent*, and shake for 5 min or until the Tablets have dispersed. Centrifuge at 3000 rpm for 10 min, and pass through a suitable filter of a 0.45-μm pore size.

Chromatographic system

(See [Chromatography \(621\)](#), [General Procedures](#), [Thin-Layer Chromatography](#))

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Developing solvent system: Methylene chloride, alcohol, and triethylamine (10:2:1)

Analysis

Sample: *Standard solution* and *Sample solution*

Acceptance criteria: The R_f value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*. ▲_{2S} (USP41)

Change to read:

• ▲A. ▲_{2S} (USP41) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲ B. The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲_{2S} (USP41)

ASSAY

Change to read:

• PROCEDURE

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

Mobile phase: [Isopropyl alcohol](#) and *Solution A* (10:90)

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

Standard stock solution: 0.2 mg/mL of [USP Naratriptan Hydrochloride RS](#) in 0.1 N [sodium hydroxide](#)

Standard solution: 0.02 mg/mL of [USP Naratriptan Hydrochloride RS](#) in *Solution A* from *Standard stock solution*

Sample solution: Nominally ($L/50$) mg/mL of naratriptan, where L is the label claim in mg/Tablet, prepared as follows. Transfer 5 Tablets into an amber 250-mL volumetric flask, add 30 mL of 0.1 N [sodium hydroxide](#), and shake on a wrist-action shaker for at least 30 min. Sonicate for 10 min with regular vigorous swirling of the flask. Add about 170 mL of *Solution A*. Allow to cool to room temperature and dilute with *Solution A* to volume. Centrifuge a portion of this solution at 3500 rpm for about 10 min, and pass through a suitable filter of 0.45-μm pore size, discarding the first 3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 224 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm. ▲_{2S} (USP41)

Column: 4.6-mm × 15-cm; 5-μm packing [L11](#)

Flow rate: 1.3 mL/min

Injection volumes

System suitability solution: 10 µL

Standard solution: 50 µL

Tablets labeled to contain 1 mg of naratriptan: 50 µL

Tablets labeled to contain 2.5 mg of naratriptan: 20 µL

▲**Run time:** NLT 1.5 times of the retention time of naratriptan ▲_{2S} (USP41)

System suitability

Samples: *System suitability solution and Standard solution*

[NOTE—The relative retention times for 3-(1-methylpiperidin-4-yl)-1H-indole (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 naratriptan related compound A and naratriptan and between naratriptan related compound B and naratriptan, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of naratriptan ($C_{17}H_{25}N_3O_2S$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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 = nominal concentration of naratriptan in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of naratriptan, 335.47

M_{r2} = molecular weight of naratriptan hydrochloride, 371.93

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 500 mL, deaerated

Apparatus 1: 100 rpm

Time: 15 min

Standard solution: [USP Naratriptan Hydrochloride RS](#) in *Medium*

[NOTE—Do not sonicate the *Standard solution* to dissolve. Dissolve [USP Naratriptan Hydrochloride RS](#) with *Medium* at about 37°.]

Sample solution: Filter portions of the solution under test and dilute with *Medium*, if necessary.

Instrumental conditions

▲(See [Ultraviolet-Visible Spectroscopy \(857\)](#).) ▲_{2S} (USP41)

Mode: UV

Analytical wavelength: 226–236 nm

Analysis

Samples: *Standard solution and Sample solution*

Determine the labeled amount of naratriptan ($C_{17}H_{25}N_3O_2S$) dissolved from the difference between the first derivative absorbance values at the wavelengths of maximum and minimum in the range from 226 to 236 nm on the *Sample solution*, suitably diluted with *Medium*, if necessary, in comparison with the *Standard solution*.

Tolerances: NLT 80% (Q) of the labeled amount of naratriptan ($C_{17}H_{25}N_3O_2S$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

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

Solution B: [Acetonitrile](#)

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

Table 1