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Vigabatrin Tablets

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DEFINITION

Vigabatrin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of vigabatrin ($C_6H_{11}NO_2$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Grind an appropriate number of Tablets to prepare a 50-mg/mL solution of vigabatrin in [water](#). Pass a portion of the solution through a suitable filter, and prepare a 2-mg/mL solution by mixing a suitable portion of the filtrate with [acetone](#). Evaporate the solution to dryness in a stream of nitrogen. Prepare a potassium bromide pellet using a suitable amount of the residue. Alternatively, the *Sample* may be prepared by directly mixing an amount of finely ground Tablets (NLT 2) equivalent to about of 3 mg of vigabatrin with about 200 mg of [potassium bromide](#).

Acceptance criteria: The IR spectrum of the *Sample* is consistent with a similarly prepared pellet of [USP Vigabatrin RS](#).

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

ASSAY

• PROCEDURE

Buffer: 3.4 g/L of [potassium phosphate, monobasic](#) in [water](#)

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (4:40:1000). Adjust with [phosphoric acid](#) to a pH of 2.8.

System suitability solution: 1.0 mg/mL of [USP Vigabatrin RS](#) and 12 µg/mL of [USP Vigabatrin Related Compound A RS](#) in *Mobile phase*

Standard solution: 1.0 mg/mL of [USP Vigabatrin RS](#) in *Mobile phase*

Sample stock solution: Nominally 5.0 mg/mL of vigabatrin from Tablets (NLT 10) prepared as follows. Transfer a suitable number of Tablets to a suitable volumetric flask. Add *Mobile phase* to about 80% of the flask volume, and stir for 1 h to give a uniform dispersion of fine particulate. Dilute with *Mobile phase* to volume, and pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 1.0 mg/mL of vigabatrin from the *Sample stock solution* and *Mobile phase*. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 10-µm packing [L9](#)

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

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

[NOTE—The relative retention times for vigabatrin related compound A and vigabatrin are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between vigabatrin related compound A and vigabatrin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of vigabatrin ($C_6H_{11}NO_2$) in the portion of Tablets taken:

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

r_U = peak response of vigabatrin from the *Sample solution*

r_S = peak response of vigabatrin from the *Standard solution*

C_S = concentration of [USP Vigabatrin RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Mobile phase: Dissolve 6 g of [sodium phosphate, monobasic](#) in 800 mL of [water](#). Add 100 mL of [acetonitrile](#), and dilute with [water](#) to 1 L. Adjust with [phosphoric acid](#) to a pH of 2.3.

System suitability solution: 0.6 mg/mL of [USP Vigabatrin RS](#) and 6 µg/mL of [USP Vigabatrin Related Compound A RS](#) in *Mobile phase*

Standard solution: (L/900) mg/mL of [USP Vigabatrin RS](#) in [water](#)

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 10-µm packing [L9](#)

Flow rate: 1.0 mL/min

Injection volume: 50 µL

System suitability

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

[NOTE—The relative retention times for vigabatrin related compound A and vigabatrin are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between vigabatrin related compound A and vigabatrin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage (Q) of the labeled amount of vigabatrin ($C_6H_{11}NO_2$) dissolved:

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

r_U = peak response of vigabatrin from the *Sample solution*

r_S = peak response of vigabatrin from the *Standard solution*

C_S = concentration of [USP Vigabatrin RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*

Tolerances: NLT 75% (Q) of the labeled amount of vigabatrin ($C_6H_{11}NO_2$) is dissolved in 30 min.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm

Time: 30 min