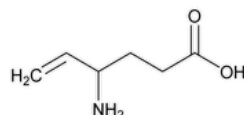


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Vigabatrin



$C_6H_{11}NO_2$ 129.16

5-Hexenoic acid, 4-amino-

4-Amino-5-hexenoic acid CAS RN®: 68506-86-5; UNII: GR120KRT6K.

DEFINITION

Vigabatrin contains NLT 98.0% and NMT 102.0% of vigabatrin ($C_6H_{11}NO_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197M ▲ (CN 1-May-2020)
- **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 [monobasic potassium phosphate](#)

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

Standard solution: 2.0 mg/mL of [USP Vigabatrin RS](#) in *Mobile phase*

System suitability solution: 12 µg/mL of [USP Vigabatrin Related Compound A RS](#) in the *Standard solution*

Sample solution: 2.0 mg/mL of Vigabatrin in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25.0-cm; 10-µm packing [L9](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: NLT 1.8 times the retention time of vigabatrin

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for vigabatrin related compound A and vigabatrin are about 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between vigabatrin related compound A and vigabatrin

Relative standard deviation: NMT 1.0% for the vigabatrin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of vigabatrin ($C_6H_{11}NO_2$) in the portion of Vigabatrin 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 Vigabatrin RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Vigabatrin in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• LIMIT OF γ -AMINOBUTYRIC ACID

Solution A: 1.6 g/L of [9-fluorenylmethyl chloroformate](#) (FMOC) in acetone

Buffer A: 4.1 g/L of [anhydrous sodium acetate](#). Adjust with [glacial acetic acid](#) to a pH of 4.2.

Buffer B: 31 g/L of [boric acid](#). Adjust with 0.5 g/mL of [sodium hydroxide](#) to a pH of 7.7.

Mobile phase: [Acetonitrile](#) and *Buffer A* (32:68)

System suitability stock solution: 2.0 mg/mL of [USP Vigabatrin RS](#) and 4 μ g/mL of [USP \$\gamma\$ -Aminobutyric Acid RS](#) in [water](#)

System suitability solution: Transfer 1.0 mL of *System suitability stock solution* to a suitable container. Pipet 2 mL of *Buffer B* into the container, and mix. Pipet 3 mL of *Solution A* into the container, mix, and allow to stand for 5 min. Pipet 3 mL of [ethyl acetate](#) into the container, shake for a few seconds, and allow the layers to separate. Use the lower layer within 8 h of preparation.

Standard stock solution: 4 μ g/mL of [USP \$\gamma\$ -Aminobutyric Acid RS](#) in [water](#)

Standard solution: Transfer 1.0 mL of *Standard stock solution* to a suitable container. Pipet 2 mL of *Buffer B* into the container, and mix. Pipet 3 mL of *Solution A* into the container, mix, and allow to stand for 5 min. Pipet 3 mL of [ethyl acetate](#) into the container, shake for a few seconds, and allow the layers to separate. Use the lower layer within 8 h of preparation.

Sample stock solution: 2.0 mg/mL of Vigabatrin in [water](#)

Sample solution: Transfer 1.0 mL of *Sample stock solution* to a suitable container. Pipet 2 mL of *Buffer B* into the container, and mix. Pipet 3 mL of *Solution A* into the container, mix, and allow to stand for 5 min. Pipet 3 mL of [ethyl acetate](#) into the container, shake for a few seconds, and allow the layers to separate. Use the lower layer within 8 h of preparation.

Chromatographic system

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

Mode: LC

Detector: UV 263 nm

Column: 4.6-mm $\times$ 15.0-cm; 5- μ m packing [L11](#)

Flow rate: 1 mL/min

Injection volume: 25 μ L

Run time: NLT 1.5 times the retention time of FMOC-vigabatrin

System suitability

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

[NOTE—The relative retention times for (9-fluorenyl)methanol (FMOC-OH), FMOC- γ -aminobutyric acid, and FMOC-vigabatrin are about 0.5, 0.6, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between FMOC-OH and FMOC- γ -aminobutyric acid, *System suitability solution*

Relative standard deviation: NMT 2.0% for the FMOC- γ -aminobutyric acid peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of γ -aminobutyric acid in the portion of Vigabatrin taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response of FMOC- γ -aminobutyric acid from the *Sample solution*

r_s = peak response of FMOC- γ -aminobutyric acid from the *Standard solution*

C_s = concentration of [USP \$\gamma\$ -Aminobutyric Acid RS](#) in the *Standard stock solution* (mg/mL)

C_u = concentration of Vigabatrin in the *Sample stock solution* (mg/mL)

Acceptance criteria: NMT 0.2% of γ -aminobutyric acid

• ORGANIC IMPURITIES

Buffer: 58.5 g/L of [monobasic sodium phosphate](#) in dilute [phosphoric acid](#) (23 in 1000)