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Vigabatrin for Oral Solution

DEFINITION
Vigabatrin for Oral Solution contains NLT 95.0% and NMT 105.0% of the labeled amount of vigabatrin ($C_6H_{11}NO_2$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Combine an appropriate number of Vigabatrin for Oral Solution packets to prepare a 50 mg/mL solution of vigabatrin in water. Pass a portion 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 (KBr) pellet using a suitable amount of the residue.

Alternatively, the *Sample* may be prepared by directly mixing an amount of the contents of NLT 2 packets of Vigabatrin for Oral Solution equivalent to about 3 mg of vigabatrin with about 200 mg of potassium bromide.

Acceptance criteria: The spectrum of the *Sample* corresponds to that of the spectrum of USP Vigabatrin RS prepared in a similar manner.

• **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 in water

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

System suitability solution: 2 mg/mL of USP Vigabatrin RS and 12 µg/mL of USP Vigabatrin Related Compound A RS in *Mobile phase*

Standard solution: 2.0 mg/mL of USP Vigabatrin RS in *Mobile phase*

Sample solution: Nominally 2.0 mg/mL of vigabatrin from the contents of NLT 10 Vigabatrin for Oral Solution packets prepared as follows. Combine the contents from the packets, and transfer a suitable amount of the powder equivalent to NLT 200 mg of vigabatrin to a suitable volumetric flask. Dilute with *Mobile phase* to volume.

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: 20 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 peaks, *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 Vigabatrin for Oral Solution 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: 95.0%–105.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Buffer: 1.5 g/L of ammonium acetate in water

Mobile phase: Acetonitrile and *Buffer* (5:95)

System suitability solution: 0.1 mg/mL each of USP Vigabatrin RS, USP Vigabatrin Related Compound A RS, USP Vigabatrin Related Compound B RS, and USP Povidone RS in *Mobile phase*

Sensitivity solution: 0.01 mg/mL of USP Vigabatrin Related Compound A RS in *Mobile phase*

Standard solution: 0.07 mg/mL of USP Vigabatrin Related Compound A RS in *Mobile phase*

Sample solution: Nominally 22 mg/mL of vigabatrin prepared as follows. Transfer a suitable amount of powder from the combined contents of NLT 10 Vigabatrin for Oral Solution packets, equivalent to NLT 220 mg of vigabatrin, to a suitable volumetric flask. Add *Mobile phase* to 80% of the volume of the flask. Sonication may be used to aid in dissolution. Allow the resulting solution to cool to room temperature. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: 12 times the retention time of the vigabatrin peak

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

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

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Vigabatrin for Oral Soution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of vigabatrin related compound A from the *Standard solution*

C_S = concentration of USP Vigabatrin Related Compound A in the *Standard solution*

C_U = nominal concentration of vigabatrin in the *Sample solution*

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor[a]	Acceptance Criteria, NMT (%)
Vigabatrin	0.12	—	—
Vigabatrin related compound B[b]	0.13	—	—
Povidone[c]	0.25	—	—
Vigabatrin related compound A	1.0	1.0	0.15
Any individual unspecified degradation product	—	0.026	0.15
Total impurities	—	—	0.5

[a] RRF relative to vigabatrin related compound A.

[b] Included for peak identification only. Not to be included in *Total impurities*.

[c] Povidone is due to excipient. Included for identification only. Not to be included in *Total impurities*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Povidone RS

USP Vigabatrin RS

USP Vigabatrin Related Compound A RS

5-Vinylpyrrolidin-2-one.

C_6H_9NO 111.14

USP Vigabatrin Related Compound B RS

(*E*)-2-(2-Aminoethyl)but-2-enoic acid hydrochloride.

$C_6H_{11}NO_2 \cdot HCl$ 165.62

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VIGABATRIN FOR ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

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