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Gabapentin Capsules

DEFINITION

Gabapentin Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of gabapentin ($C_9H_{17}NO_2$).

IDENTIFICATION

Change to read:

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

Sample: Empty the contents of NLT 10 Capsules, and grind to a fine powder. Use a quantity of the powder, equivalent to 2 mg of gabapentin, and 200 mg of potassium bromide.

Acceptance criteria: Meet the requirements

• **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**

Diluent: 1.2 g/L of monobasic potassium phosphate in water. Adjust with 5 N potassium hydroxide to a pH of 6.9.

Mobile phase: Dissolve 1.2 g of monobasic potassium phosphate in 940 mL water. Adjust with 5 N potassium hydroxide to a pH of 6.9. Add 60 mL of acetonitrile and stir.

Standard solution: 4.0 mg/mL of USP Gabapentin RS in *Diluent*

Sample solution: Nominally 4.0 mg/mL of gabapentin, from the contents of NLT 20 Capsules, equivalent to 100 mg of gabapentin, in *Diluent*. Sonication for about 60 s may be necessary to dissolve the contents.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 7000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of gabapentin ($C_9H_{17}NO_2$) in the portion of Capsules 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 Gabapentin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.06 N hydrochloric acid (prepared by adding 51 mL of hydrochloric acid to 10 L of water); 900 mL

Apparatus 2: 50 rpm

Time: 20 min

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

Mobile phase: Prepare as directed in the *Assay*.

Standard solution: 0.0011*L* mg/mL of USP Gabapentin RS in the *Medium*, where *L* is the label claim in mg/Capsule

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.2 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 7000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of gabapentin ($C_9H_{17}NO_2$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of the *Medium* in the dissolution vessel, 900 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (*Q*) of the labeled amount of gabapentin ($C_9H_{17}NO_2$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Diluent: Prepare as directed in the *Assay*.

Solution A: Dissolve 1.2 g of monobasic potassium phosphate in 940 mL water. Adjust with 5 N potassium hydroxide to a pH of 6.9. Add 60 mL of acetonitrile and stir.

Solution B: Dissolve 1.2 g of monobasic potassium phosphate in 700 mL water. Adjust with 5 N potassium hydroxide to a pH of 6.9. Add 300 mL of acetonitrile and stir.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	100	0
4.0	100	0
45.0	0	100
45.1	100	0
50.0	100	0

Standard solution: 0.04 mg/mL each of USP Gabapentin RS and USP Gabapentin Related Compound A RS in *Diluent*

Sample solution: Nominally 20 mg/mL of gabapentin, from the contents of NLT 20 Capsules, equivalent to 500 mg of gabapentin, in *Diluent*. Sonication for about 30 s may be necessary.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the gabapentin peak

Relative standard deviation: NMT 5.0% for gabapentin and gabapentin related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of gabapentin related compound A in the portion of Capsules taken:

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

r_U = peak response for gabapentin related compound A from the *Sample solution*

r_S = peak response for gabapentin related compound A from the *Standard solution*

C_S = concentration of USP Gabapentin Related Compound A RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other unspecified degradation product, relative to gabapentin content, in the portion of Capsules taken:

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

r_U = peak response for each unspecified impurity from the *Sample solution*

r_S = peak response for gabapentin from the *Standard solution*

C_S = concentration of USP Gabapentin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Gabapentin related compound A: NMT 0.4%

Any individual unspecified impurity: NMT 0.1%

Total impurities: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

USP Gabapentin RS

USP Gabapentin Related Compound A RS

2-Aza-spiro[4.5]decan-3-one.

$C_9H_{15}NO$ 153.22

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

Topic/Question	Contact	Expert Committee
GABAPENTIN CAPSULES	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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