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Gabapentin Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-gabapentin-tabs-20241227.

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

IDENTIFICATION
• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**
Sample: Grind at least 20 Tablets to a fine powder. Use an amount of powder equivalent to 2 mg of gabapentin and 200 mg of dry potassium bromide.
• **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 of water. Adjust with 5 N potassium hydroxide to a pH of 6.9. Add 60 mL of acetonitrile, and stir. Filter and degas.
Standard solution: 4.0 mg/mL of USP Gabapentin RS in *Diluent*
Sample solution: 4.0 mg/mL of gabapentin from NLT 20 finely powdered Tablets in *Diluent*
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 size: 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% of gabapentin
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of $C_9H_{17}NO_2$ in the portion of Tablets taken:

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

r_U = peak response 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
Change to read:
• **Dissolution ⟨711⟩**
Test 1
Medium: 0.06 N hydrochloric acid (51 mL of hydrochloric acid in 10 L of water); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

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

Determine the amount of $C_9H_{17}NO_2$ dissolved by using the following method.

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/Tablet

Chromatographic system: Proceed as directed for the *Assay*.

Injection size: 100 µL for the Tablets labeled to contain 100, 300, or 400 mg; 50 µL for Tablets labeled to contain 600 or 800 mg

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 5000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_9H_{17}NO_2$ dissolved:

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

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*, 900 mL

L = Tablet label claim in mg

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

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

Medium, Apparatus 2, Mobile phase, Standard solution, Sample solution, Chromatographic system, and **Analysis:** Proceed as directed for *Test 1*.

Time: 30 min

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

▲**Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: 0.1 N hydrochloric acid; 500 mL, deaerated, if necessary

Apparatus 2: 50 rpm

Time: 30 min

Buffer: Dissolve 1.2 g of monobasic potassium phosphate in 940 mL of water. Adjust with 5 N potassium hydroxide to a pH of 6.9.

Mobile phase: Acetonitrile and *Buffer* (60:940)

Standard solution: (*L*/500) mg/mL of USP Gabapentin RS in *Medium*, where *L* is the label claim in mg/Tablet. Sonicate to dissolve, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained.

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: 10 µL

Run time: NLT 2.3 times the retention time of gabapentin

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage 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 of gabapentin from the *Sample solution*

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

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

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of gabapentin ($C_9H_{17}NO_2$) is dissolved.▲ (RB 1-Jan-2025)

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

IMPURITIES

Organic Impurities

• **Procedure**

Diluent: Prepare as directed in the *Assay*.

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

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

Mobile phase: See the gradient table below.

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: Equivalent to 20 mg/mL of gabapentin, from NLT 20 powdered Tablets, in *Diluent*. [Note—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 size: 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 peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of gabapentin related compound A in the portion of Tablets 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 the gabapentin content in the portion of Tablets 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.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **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 TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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