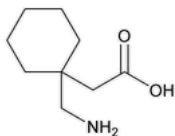


Status: Currently Official on 14-Feb-2025  
 Official Date: Official as of 01-May-2020  
 Document Type: USP Monographs  
 DocId: GUID-5C05209E-7DB0-45F6-8654-30CA734A6A56\_7\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M34587\\_07\\_01](https://doi.org/10.31003/USPNF_M34587_07_01)  
 DOI Ref: js3ox

© 2025 USPC  
 Do not distribute

# Gabapentin



$C_9H_{17}NO_2$  171.24

Cyclohexanecarboxylic acid, 1-(aminomethyl)-;

1-(Aminomethyl)cyclohexanecarboxylic acid CAS RN<sup>®</sup>: 60142-96-3; UNII: 6CW7F3G59X.

## DEFINITION

Gabapentin contains NLT 98.0% and NMT 102.0% of gabapentin ( $C_9H_{17}NO_2$ ), calculated on the anhydrous basis.

## IDENTIFICATION

**Change to read:**

- **A.** **▲** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197A or 197K **▲** (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

**Diluent:** 2.32 g/L of [monobasic ammonium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.0.

**Buffer:** 0.58 g/L of [monobasic ammonium phosphate](#) and 1.83 g/L of [sodium perchlorate](#) in [water](#). Adjust with [perchloric acid](#) to a pH of 1.8.

**Mobile phase:** [Acetonitrile](#) and *Buffer* (24:76)

**Standard solution:** 14.0 mg/mL of [USP Gabapentin RS](#) in *Diluent*

**System suitability solution:** 2.3 mg/mL of [USP Gabapentin RS](#) from the *Standard solution* in *Diluent*

**Sample solution:** 14 mg/mL of Gabapentin in *Diluent*

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 215 nm

**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)

**Column temperature:** 40°

**Flow rate:** 1 mL/min

**Injection volume:** 20 μL

**Run time:** NLT 5 times the retention time of gabapentin

### System suitability

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

### Suitability requirements

**Column efficiency:** NLT 1900 theoretical plates for the gabapentin peak, *System suitability solution*

**Relative standard deviation:** NMT 0.73%, *Standard solution*

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of gabapentin ( $C_9H_{17}NO_2$ ) in the portion of Gabapentin 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)

$C_U$  = concentration of Gabapentin in the *Sample solution* (mg/mL)

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

#### IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1%
- **EARLY-ELUTING ORGANIC IMPURITIES**

**Diluent, Buffer, and Mobile phase:** Prepare as directed in the Assay.

**System suitability stock solution:** 1.4 mg/mL of [USP Gabapentin Related Compound A RS](#) and 0.84 mg/mL of [USP Gabapentin Related Compound B RS](#) in [methanol](#)

**System suitability solution:** Dissolve a suitable quantity of [USP Gabapentin RS](#) in *Diluent* in a suitable volumetric flask, and add an appropriate volume of *System suitability stock solution* to obtain a solution containing 14.0 mg/mL of [USP Gabapentin RS](#), 14 µg/mL of [USP Gabapentin Related Compound A RS](#), and 8.4 µg/mL of [USP Gabapentin Related Compound B RS](#) in *Diluent*. Inject within 24 h.

**Standard solution:** 0.0084 mg/mL of [USP Gabapentin Related Compound E RS](#) in *Diluent*

**Sample solution:** 14 mg/mL of Gabapentin in *Diluent*. Inject within 24 h.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 215 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing [L1](#)

#### Temperatures

**Autosampler:** 5 ± 2°

**Column:** 40°

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

**Run time:** NLT 5 times the retention time of gabapentin

#### System suitability

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

#### Suitability requirements

**Resolution:** NLT 2.3 between gabapentin related compound A and gabapentin related compound B, *System suitability solution*

**Relative standard deviation:** NMT 5.0% for gabapentin related compound E, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of any impurity in the portion of Gabapentin taken:

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

$r_U$  = peak response of any impurity from the *Sample solution*

$r_S$  = peak response of gabapentin related compound E from the *Standard solution*

$C_S$  = concentration of [USP Gabapentin Related Compound E RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Gabapentin in the *Sample solution* (mg/mL)

$F$  = relative response factor (see [Table 1](#))

**Acceptance criteria:** See [Table 1](#).

**Table 1**

| Name                          | Relative Retention Time <sup>a</sup> | Relative Response Factor <sup>b</sup> | Acceptance Criteria, NMT (%) |
|-------------------------------|--------------------------------------|---------------------------------------|------------------------------|
| Gabapentin                    | 1.0                                  | —                                     | —                            |
| Gabapentin related compound E | 2.9                                  | 1.0                                   | 0.10                         |
| Gabapentin related compound A | 3.5                                  | 5.3                                   | 0.1                          |
| Gabapentin related compound B | 3.8                                  | 0.35                                  | 0.06                         |



Documents

Document Sharing Hub