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Add the following:

▲Gabapentin Compounded Oral Suspension

DEFINITION

Gabapentin Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of gabapentin ($C_9H_{17}NO_2$).

Prepare Gabapentin Compounded Oral Suspension 100 mg/mL from powder as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Gabapentin capsules[a] or Gabapentin powder, equivalent to	15 g
Vehicle: Oral Mix,[b] a sufficient quantity to make	150 mL

[a] Gabapentin 300-mg capsules, Apotex Inc., Weston, Ontario.

[b] Medisca Pharmaceutique Inc., Montréal, Quebec.

Transfer the *Gabapentin powder* or empty the contents of the capsules into a suitable container and triturate to a fine powder. Add a small amount of *Vehicle*, and mix well to form a smooth paste. Add a sufficient amount of *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add a sufficient amount of *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 10 mM solution of monobasic potassium phosphate adjusted with 1 M sodium hydroxide to a pH of 6.2

Mobile phase: Acetonitrile and *Solution A* (84:16)

Standard solution: 2.5 mg/mL of USP Gabapentin RS in *Mobile phase*

Sample solution: Add 0.05 mL of Oral Suspension to 0.45 mL of methanol, and vortex for 20 s. Centrifuge at 10,000 rpm for 15 min, and transfer 0.1 mL of the supernatant to a 1.5-mL centrifuge tube. Add 0.3 mL of *Mobile phase*, vortex for 10 s, and then transfer to HPLC vials.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 3.0-mm × 10-cm; 5-µm packing L8

Temperatures

Autosampler: 5°

Column: 40°

Flow rate: 0.8 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for gabapentin is approximately 2.9 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Suspension taken:

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

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)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature. Do not refrigerate.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Gabapentin RS▲ (USP 1-Dec-2021)

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

Topic/Question	Contact	Expert Committee
GABAPENTIN COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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