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Add the following:

▲Gabapentin Compounded Cream

DEFINITION

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

Prepare Gabapentin Compounded Cream, 20 mg/g and 100 mg/g as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

To Prepare a Gabapentin Compounded Cream containing 20 mg/g of gabapentin:

Gabapentin	2 g
Propylene Glycol	5 mL
Lipoderm[a], a sufficient quantity to make	100 g

[a] PCCA, Houston, TX.

To Prepare a Gabapentin Compounded Cream containing 100 mg/g of gabapentin:

Gabapentin	10 g
Propylene Glycol	10 mL
Lipoderm[a], a sufficient quantity to make	100 g

[a] PCCA, Houston, TX.

In an appropriately sized electronic mortar and pestle container, add 50 g of *Lipoderm*, then place the *Gabapentin* and *Propylene Glycol* on top, then add sufficient *Lipoderm* to bring to final weight. Mix the mixture with an electronic mortar and pestle for 5 min on a speed of about 1500 rpm. Process through an ointment mill once at the middle setting and once at the finest setting to reduce the particle size of the active ingredient and reduce air content of the preparation. Return the mixture to the electronic mortar and pestle container and mix again for 3–5 min on a speed of about 1100 rpm.

ASSAY

• **Procedure**

Solution A: A solution of 1.44 g/L of ammonium acetate in water, adjusted using glacial acetic acid to a pH of 4.0. Pass through a polyvinyl difluoride filter of 0.22-µm pore size.

Mobile phase: *Solution A* and acetonitrile (15:85)

Standard stock solution: 2 mg/mL of USP Gabapentin RS in methanol. Sonicate for 2 min and vortex.

Standard solutions: Prepare five calibration standard solutions having the concentrations of gabapentin in *Table 1*, by diluting *Standard stock solution* with methanol.

Table 1

Assay Level	Final Concentration (mg/mL)
80%	0.32
90%	0.36
100%	0.40
110%	0.44
120%	0.48

Sample solution of 20 mg/g Gabapentin Cream: Collect about 2 mL of Cream into a 3-mL syringe, avoiding air gaps. Transfer the Cream from a 3-mL syringe into a 1-mL syringe until fully filled. Insert the piston and move to about 5 mm above the 1-mL mark. Wipe excess Cream off the outside of syringe. Weigh the full syringe and record the weight. Fill a 50-mL volumetric flask with 25 mL of methanol (wet the neck of the flask with methanol) and transfer the Cream into the flask. Weigh the empty syringe (the difference between the original and final weight should be between 900 and 1100 mg). Vortex the flask for 3 min, sonicate for 5 min, and then vortex for 2 min. Bring the flask to volume with methanol. Vortex for 2 min (the solution should be partially cloudy). Pass through a 0.45-µm polyvinylidene fluoride (PVDF) filter, discard the first 3 mL, and then transfer into an HPLC vial.

Sample solution of 100 mg/g Gabapentin Cream: Collect about 2 mL of Cream into a 3-mL syringe, avoiding air gaps. Transfer the Cream from a 3-mL syringe into a 1-mL syringe until fully filled. Insert the piston and move to about 5 mm above the 1-mL mark. Wipe excess Cream off the outside of the syringe. Weigh the full syringe and record the weight. Fill a 250-mL volumetric flask with 25 mL of methanol (wet the neck of the flask with methanol) and transfer Cream into the flask. Weigh the empty syringe (the difference between the original and final weight should be between 900 and 1100 mg). Vortex the flask for 3 min, sonicate for 5 min, and then vortex for 2 min. Bring flask to volume with methanol. Vortex for 2 min (the solution should be partially cloudy). Pass through a 0.45-µm PVDF filter, discard the first 3 mL, and then transfer into an HPLC vial.

Chromatographic system

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

Mode: LC

Detector: Evaporative light-scattering

Drift tube temperature: 50°

Gain: 8

Offset: 0 mV

Sampling rate: 100 ms

Filter: 5 s

Gas: 3.5 bar

Column: 4.6-mm × 15-cm; 3.5-µm packing L68

Temperatures

Autosampler: 10°

Column: 50°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: 100% calibration *Standard solution* (0.40 mg/mL)

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.5% for six standard injections

Analysis

Samples: Each of the *Standard solutions* and *Sample solution* in triplicate

Identify the gabapentin peaks in the chromatogram of the *Sample solution* by comparison with the chromatograms obtained from the *Standard solutions*. Measure the areas of the gabapentin peaks. Plot the logarithms of the average peak area versus the logarithms of the concentrations, in mg/mL, of gabapentin obtained from the *Standard solutions* and determine the linear regression line using a least-squares analysis. The correlation coefficient for the linear regression line is NLT 0.995. From the graphs so obtained, determine the concentration, *C*, in mg/mL, of the gabapentin in the *Sample solution*.

Calculate the percentage of the labeled amount of gabapentin ($C_9H_{17}NO_2$) in the portion of Cream taken:

$$\text{Result} = (CV/W) \times 100$$

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

V = volume of Gabapentin in the *Sample solution* (mL)

W = weight of Cream in the *Sample solution* (mg)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

For 20 mg/g Cream: 5.8–6.8

For 100 mg/g Cream: 6.0–7.0

Appearance: Opaque, white cream

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a metered-dose, plastic container. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days from the date on which it was compounded when stored at controlled room temperature. Preparations have passed *Antimicrobial Effectiveness Testing* ⟨51⟩.

• **Labeling:** Label it for external use only and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Gabapentin RS

▲ (USP 1-Dec-2023)

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

Topic/Question	Contact	Expert Committee
GABAPENTIN COMPOUNDED CREAM	Selma Mitiche Associate Scientific Liaison	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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