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Add the following:

▲Phenytoin Compounded Topical Gel

DEFINITION

Phenytoin Compounded Topical Gel contains NLT 95.0% and NMT 105.0% of the labeled amount of phenytoin ($C_{15}H_{12}N_2O_2$).

Prepare Phenytoin Compounded Topical Gel 10 mg/g to 50 mg/g as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

For Phenytoin Compounded Topical Gel containing 10 mg/g of phenytoin:

Phenytoin	1 g
Polyethylene Glycol 300	10 g
PCCA Spira-Wash Gel,[a] a sufficient quantity to make	100 g

[a] PCCA, Houston, TX.

For Phenytoin Compounded Topical Gel containing 50 mg/g of phenytoin:

Phenytoin	5 g
Polyethylene Glycol 300	10 g
PCCA Spira-Wash Gel,[a] a sufficient quantity to make	100 g

[a] PCCA, Houston, TX.

In an appropriately sized electronic mortar and pestle container, add *Phenytoin*, *Polyethylene Glycol 300*, and sufficient *PCCA Spira-Wash Gel* to bring to final weight. Mix the mixture with an electronic mortar and pestle for 3 min at a speed of about 1450 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 and mix again for 1 min at a speed of about 1130 rpm. Package in a light-resistant calibrated dispenser.

ASSAY

• **Procedure**

Solution A: 0.1% trifluoroacetic acid in acetonitrile

Solution B: 0.1% trifluoroacetic acid in water

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	3	97
1.5	55	45
1.6	3	97

Time (min)	Solution A (%)	Solution B (%)
2.0	3	97

Standard solution: 0.05 mg/mL of USP Phenytoin RS in methanol

Sample solution

For Topical Gel 10 mg/g: Transfer 0.5 g of Topical Gel into a 50-mL centrifuge tube, add 19.5 mL of methanol, and vortex for 1 min. Sonicate for 2 min and vortex for 1 min. Centrifuge the mixture for 10 min at 6000 rpm. Transfer 2 mL of the supernatant to a 10-mL volumetric flask and dilute with methanol to volume. Centrifuge for 10 min at 14,000 rpm.

For Topical Gel 50 mg/g: Transfer 0.5 g of Topical Gel into a 50-mL centrifuge tube, add 19.5 mL of methanol, and vortex for 1 min. Sonicate for 2 min and vortex for 1 min. Centrifuge the mixture for 10 min at 6000 rpm. Transfer 0.4 mL of the supernatant to a 10-mL volumetric flask and dilute with methanol to volume. Centrifuge for 10 min at 14,000 rpm.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Temperatures

Autosampler: 8°

Column: 65°

Flow rate: 1 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for phenytoin is about 1.3 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 phenytoin ($C_{15}H_{12}N_2O_2$) in the portion of Topical Gel taken:

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

r_U = peak response of phenytoin from the *Sample solution*

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

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

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

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 7.2–8.2
- **VISCOSITY—ROTATIONAL METHODS ⟨912⟩:** 500–3500 mPa · s

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in a tight, light-resistant calibrated dispenser. Store at controlled room temperature or in a refrigerator.
- **BEYOND-USE DATE:** NMT 180 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.
- **LABELING:** Label it to indicate that it is for external use only and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Phenytoin RS▲ (USP 1-May-2020)

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

Topic/Question	Contact	Expert Committee
PHENYTOIN COMPOUNDED TOPICAL GEL	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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