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Phenobarbital Compounded Oral Suspension

DEFINITION

Phenobarbital Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of phenobarbital ($C_{12}H_{12}N_2O_3$).

Prepare Phenobarbital Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Phenobarbital tablets[a] equivalent to	1.2 g of phenobarbital
Vehicle: a 1:1 mixture of Ora-Sweet[b] (regular or sugar-free) and Ora-Plus,[b] a sufficient quantity to make	120 mL

[a] Phenobarbital 60-mg tablets, Excellium Pharmaceutical, Inc., Fairfield, NJ.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Phenobarbital tablets* in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a phenobarbital liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (30:70). Adjust with dilute sulfuric acid to a pH of 3.0.

Standard stock solution: 0.4 mg/mL of USP Phenobarbital RS in *Mobile phase*

Standard solution: 20 µg/mL of phenobarbital prepared from *Standard stock solution* and *Mobile phase*

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 20 µg/mL of phenobarbital from Oral Suspension and *Mobile phase*, and centrifuge.

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 60°

Flow rate: 1.0 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for phenobarbital is about 6.8 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phenobarbital ($C_{12}H_{12}N_2O_3$) in the portion of Oral Suspension 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 Phenobarbital RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of phenobarbital in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 115 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 Phenobarbital RS

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

Topic/Question	Contact	Expert Committee
PHENOBARBITAL COMPOUNDED ORAL SUSPENSION	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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