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Phenobarbital Oral Solution

» Phenobarbital Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of phenobarbital ($C_{12}H_{12}N_2O_3$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Phenobarbital RS

Identification—

A: Place 10 mL of Oral Solution in a separator containing 20 mL of water, add 5 mL of 1 N sodium hydroxide, and extract with two 10-mL portions of chloroform, discarding the chloroform extracts. Add 5 mL of 3 N hydrochloric acid, and extract with two 25-mL portions of chloroform, filtering the extracts through paper into a beaker. Remove the chloroform by evaporation on a steam bath, and dry the residue at 105° for 2 hours: the residue so obtained meets the requirements for *Identification* test *A* under *Phenobarbital*.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* both relative to the internal standard, as obtained in the *Assay*.

Alcohol Determination, *Method II* ⟨611⟩: between 12.0% and 15.0% of C_2H_5OH.

Assay—

pH 4.5 Buffer solution, *Mobile phase*, and *Chromatographic system*—Prepare as directed in the *Assay* under *Phenobarbital*.

Diluent—Prepare a mixture of methanol and *pH 4.5 Buffer solution* (2:1).

Internal standard solution—Dissolve a sufficient quantity of caffeine in *Diluent* to obtain a solution having a concentration of about 1.7 mg per mL.

Standard preparation—Transfer about 33 mg of USP Phenobarbital RS, accurately weighed, to a 25-mL volumetric flask containing 2.0 mL of *Internal standard solution*. Dilute with *Diluent* to volume, and mix.

Assay preparation—Transfer a quantity of Oral Solution, equivalent to about 33 mg of phenobarbital, to a 25-mL volumetric flask containing 2.0 mL of *Internal standard solution*. Dilute with *Diluent* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Phenobarbital*. Calculate the quantity, in mg, of phenobarbital ($C_{12}H_{12}N_2O_3$) in the portion of the Oral Solution taken by the formula:

$$W(R_U/R_S)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
PHENOBARBITAL ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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