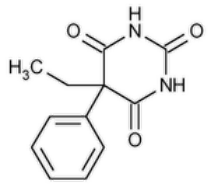
Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-7B43889A-7F73-4B88-BB73-1C563E0AD856_1_en-US
DOI: https://doi.org/10.31003/USPNF_M63400_01_01
DOI Ref: a0n6l

Phenobarbital



$C_{12}H_{12}N_2O_3$ 232.24

2,4,6(1*H*,3*H*,5*H*)-Pyrimidinetrione, 5-ethyl-5-phenyl-.

5-Ethyl-5-phenylbarbituric acid CAS RN®: 50-06-6; UNII: YQE403BP4D.

» Phenobarbital contains not less than 98.0 percent and not more than 101.0 percent of $C_{12}H_{12}N_2O_3$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference Standards ⟨11⟩—
USP Phenobarbital RS

Identification—

A: The IR absorption spectrum of a potassium bromide dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Phenobarbital RS. If a difference appears, dissolve portions of both the test specimen and the USP Reference Standard in a suitable solvent, evaporate the solutions to dryness, and repeat the test on the residues.

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

Melting Range ⟨741⟩: between 174° and 178°, but the range between beginning and end of melting does not exceed 2°.

Loss on Drying ⟨731⟩—Dry it at 105° for 2 hours: it loses not more than 1.0% of its weight.

Residue on Ignition ⟨281⟩: not more than 0.15%.

Assay—

pH 4.5 Buffer solution—Dissolve about 6.6 g of sodium acetate trihydrate and 3.0 mL of glacial acetic acid in 1000 mL of water, and adjust, if necessary, with glacial acetic acid to a pH of 4.5 ± 0.1.

Mobile phase—Prepare a filtered and degassed mixture of *pH 4.5 Buffer solution* and methanol (3:2), making adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Internal standard solution—Dissolve a sufficient quantity of caffeine in a mixture of methanol and *pH 4.5 Buffer solution* (1:1) to obtain a solution having a concentration of about 125 µg per mL.

Standard preparation—Dissolve about 20 mg of USP Phenobarbital RS, accurately weighed, in 15.0 mL of *Internal standard solution.* Sonicate if necessary.

Assay preparation—Transfer about 20 mg of Phenobarbital, accurately weighed, to a conical flask, add 15.0 mL of *Internal standard solution*, mix, and sonicate for 15 minutes. Filter through a membrane filter (0.5 µm or finer porosity) before use.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and the internal standard peaks is not less than 1.2, the tailing factor for the analyte and the internal standard peaks is not greater than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.6 for caffeine and 1.0 for phenobarbital. Calculate the quantity, in mg, of $C_{12}H_{12}N_2O_3$ in the portion of Phenobarbital taken by the formula:

$$W(R_U/R_S)$$

in which W is the weight, in mg, of USP Phenobarbital RS taken for the *Standard preparation*, and R_U and R_S are the peak response ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PHENOBARBITAL	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(5)

Current DocID: GUID-7B43889A-7F73-4B88-BB73-1C563E0AD856_1_en-US
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