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Phenobarbital Sodium

$C_{12}H_{11}N_2NaO_3$ 254.22

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

Sodium 5-ethyl-5-phenylbarbiturate CAS RN®: 57-30-7; UNII: SW9M9BB5K3.

» Phenobarbital Sodium contains not less than 98.5 percent and not more than 101.0 percent of $C_{12}H_{11}N_2NaO_3$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

USP Reference standards ⟨11⟩—

USP Phenobarbital RS

Completeness of solution—Mix 1.0 g with 10 mL of carbon dioxide-free water: after 1 minute, the solution is clear and free from undissolved solid.

Identification—

A: Dissolve about 50 mg of Phenobarbital Sodium in 15 mL of water in a separator, add 2 mL of hydrochloric acid, shake, and extract the liberated phenobarbital with four 25-mL portions of chloroform. Filter the combined extracts through a pledget of cotton or other suitable filter into a beaker, and wash the separator and the filter with several small portions of chloroform. Evaporate a 50-mL portion of the chloroform solution of phenobarbital on a steam bath with the aid of a current of air. Add 10 mL of ether, again evaporate, and dry the residue at 105° for 2 hours: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Phenobarbital RS.

B: Ignite about 200 mg: the residue effervesces with acids, and responds to the tests for *Sodium* ⟨191⟩.

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

pH ⟨791⟩**:** between 9.2 and 10.2, in the solution prepared in the test for *Completeness of solution*.

Loss on drying ⟨731⟩—Dry it at 150° for 4 hours: it loses not more than 7.0% of its weight.

Other requirements—Where the label states that Phenobarbital Sodium is sterile, it meets the requirements for *Sterility Tests* ⟨71⟩ and for *Bacterial endotoxins* under *Phenobarbital Sodium for Injection.* Where the label states that Phenobarbital Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Phenobarbital Sodium for Injection.*

Assay—

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

Assay preparation—Transfer about 22 mg of Phenobarbital Sodium, accurately weighed, to a conical flask, add 15.0 mL of *Internal standard solution*, mix, and sonicate for 15 minutes. Pass through a membrane filter having a 0.5-µm or finer porosity before use.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Phenobarbital*. Calculate the quantity, in mg, of $C_{12}H_{11}N_2NaO_3$ in the portion of Phenobarbital Sodium taken by the formula:

$$(254.22/232.24)(W)(R_U/R_S)$$

in which 254.22 and 232.24 are the molecular weights of phenobarbital sodium and phenobarbital, respectively; and the other terms are as defined therein.

Topic/Question	Contact	Expert Committee
PHENOBARBITAL SODIUM	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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