Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-2718E37D-A767-430E-A636-39301715DD93_1_en-US
DOI: https://doi.org/10.31003/USPNF_M63430_01_01
DOI Ref: d4zop

Phenobarbital Tablets

» Phenobarbital Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{12}H_{12}N_2O_3$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Phenobarbital RS

Identification—

A: Triturate a quantity of finely powdered Tablets, equivalent to about 60 mg of phenobarbital, with 50 mL of chloroform, and filter. Evaporate the clear filtrate to dryness, and dry at 105° for 2 hours: the residue so obtained responds to *Identification* test *A* under *Phenobarbital*.

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*.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{12}H_{12}N_2O_3$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 240 nm on filtered portions of the solution under test, suitably diluted with pH 9.6 alkaline borate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*), in comparison with a Standard solution having a known concentration of USP Phenobarbital RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{12}H_{12}N_2O_3$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

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—Weigh and finely powder not fewer than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 20 mg of phenobarbital, add 15.0 mL of *Internal standard solution*, mix, and sonicate for 15 minutes. Filter 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 $C_{12}H_{12}N_2O_3$ in the portion of Tablets 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 TABLETS	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-2718E37D-A767-430E-A636-39301715DD93_1_en-US
DOI: https://doi.org/10.31003/USPNF_M63430_01_01
DOI ref: d4zop