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Phenobarbital Sodium Injection

» Phenobarbital Sodium Injection is a sterile solution of Phenobarbital Sodium in a suitable solvent. Phenobarbital may be substituted for the equivalent amount of Phenobarbital Sodium, for adjustment of the pH. The Injection contains the equivalent of not less than 90.0 percent and not more than 105.0 percent of the labeled amount of $C_{12}H_{11}N_2NaO_3$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

Labeling—The label indicates that the Injection is not to be used if it contains a precipitate.

USP Reference standards ⟨11⟩—

USP Phenobarbital RS

Identification—

A: Transfer to a separator a volume of Injection, equivalent to about 50 mg of phenobarbital sodium, add 15 mL of water, 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: 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*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.3 USP Endotoxin Unit per mg of phenobarbital sodium.

pH ⟨791⟩: between 9.2 and 10.2.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

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

Standard preparation—Transfer about 15 mg of USP Phenobarbital RS, accurately weighed, to a 50-mL volumetric flask, add 25 mL of *Mobile phase*, and sonicate if necessary to dissolve. Add 15.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix to obtain a solution having a known concentration of about 0.3 mg of USP Phenobarbital RS per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 65 mg of phenobarbital sodium, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 25.0 mL of this solution to a 50-mL volumetric flask, add 15.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix.

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 each mL of the Injection taken by the formula:

$$(254.22/232.24)(4W/V)(R_U/R_S)$$

in which 254.22 and 232.24 are the molecular weights of phenobarbital sodium and phenobarbital, respectively, V is the volume, in mL, of Injection taken, and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
PHENOBARBITAL SODIUM INJECTION	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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