Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-E227626A-91B0-44BD-B7CB-F45DD2AED691_3_en-US
DOI: https://doi.org/10.31003/USPNF_M62410_03_01
DOI Ref: x58dn

Pentobarbital Sodium Injection

» Pentobarbital Sodium Injection is a sterile solution of Pentobarbital Sodium in a suitable solvent. Pentobarbital may be substituted for the equivalent amount of Pentobarbital Sodium, for adjustment of the pH. The Injection contains the equivalent of not less than 92.0 percent and not more than 108.0 percent of the labeled amount of $C_{11}H_{17}N_2NaO_3$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass. The Injection may be packaged in 50-mL containers.

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

USP Reference standards ⟨11⟩—
USP Pentobarbital RS

Identification—The 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.*

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.8 USP Endotoxin Unit per mg of pentobarbital sodium.

pH ⟨791⟩: between 9.0 and 10.5.

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

Assay—

Mobile phase—Prepare a filtered and degassed pH 3.5 mixture of 0.01 M monobasic potassium phosphate and acetonitrile (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Pentobarbital RS in *Mobile phase,* and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Quantitatively dilute a suitable volume of Injection with *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 214-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′*, is not less than 2.5; the column efficiency is not less than 15,000 theoretical plates; the tailing factor is not more than 1.5; 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. Calculate the percentage of $C_{11}H_{17}N_2NaO_3$ in the portion of Injection taken by the formula:

$$100(248.25/226.27)(C_S/C_U)(r_U/r_S)$$

in which 248.25 and 226.27 are the molecular weights of pentobarbital sodium and pentobarbital, respectively; C_S is the concentration, in mg per mL, of USP Pentobarbital RS in the *Standard preparation;* C_U is the final concentration, in mg per mL, of the *Assay preparation;* and r_U and r_S are the peak areas 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
PENTOBARBITAL 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 32(2)

Current DocID: GUID-E227626A-91B0-44BD-B7CB-F45DD2AED691_3_en-US
Previous DocID: GUID-E227626A-91B0-44BD-B7CB-F45DD2AED691_1_en-US
DOI: https://doi.org/10.31003/USPNF_M62410_03_01
DOI ref: x58dn