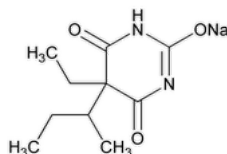


Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-20653A04-B2A2-42D5-A4BC-771F13789A57_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M10650_04_01
 DOI Ref: mnq8y

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Butabarbital Sodium



$C_{10}H_{15}N_2NaO_3$ 234.23

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

Sodium 5-sec-butyl-5-ethylbarbiturate CAS RN®: 143-81-7; UNII: 9WTD50I918.

DEFINITION

Butabarbital Sodium contains NLT 98.2% and NMT 100.5% of butabarbital sodium ($C_{10}H_{15}N_2NaO_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)

Sample: 150 mg of Butabarbital Sodium

Analysis: Transfer the *Sample* to a suitable separator, dissolve in 10 mL of water, and add 15 mL of 3 N hydrochloric acid. Extract with three 20-mL portions of chloroform, filter the extracts through anhydrous sodium sulfate, and collect the extracts in a suitable beaker. Evaporate the combined extracts on a steam bath with the aid of a current of air to dryness, and dry the residue at 105° for 2 h.

Acceptance criteria: Meets the requirements

Change to read:

- **B.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U▲](#) (CN 1-MAY-2020)

Analytical wavelength: 240 nm

Buffer: pH 9.6 alkaline borate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#))

Standard solution: 10 µg/mL of [USP Butabarbital RS](#) in *Buffer*

Sample solution: 10 µg/mL of Butabarbital Sodium in *Buffer*

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

- **C.** [IDENTIFICATION TESTS—GENERAL, Sodium \(191\)](#)

Sample: 100 mg of Butabarbital Sodium

Analysis: Ignite the *Sample*, and proceed as directed in the chapter using the residue.

Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**

Buffer: pH 9.6 alkaline borate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#))

Standard stock solution: 0.125 mg/mL of [USP Butabarbital RS](#) in *Buffer*

Standard solution: 0.0125 mg/mL of [USP Butabarbital RS](#) from *Standard stock solution* in *Buffer*

Sample stock solution: 0.140 mg/mL of Butabarbital Sodium in *Buffer*

Sample solution: 0.0140 mg/mL from *Sample stock solution* in *Buffer*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 240 nm

Blank: *Buffer*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Concomitantly determine the absorbances of the solutions.

Calculate the percentage of butabarbital sodium ($C_{10}H_{15}N_2NaO_3$) in the portion of Butabarbital Sodium taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Butabarbital RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Butabarbital Sodium in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of butabarbital sodium, 234.23

M_{r2} = molecular weight of butabarbital, 212.25

Acceptance criteria: 98.2%–100.5% on the dried basis

IMPURITIES

• ORGANIC IMPURITIES

Diluent: Chloroform and methanol (50:50)

Standard solution A: 4.0 mg/mL of [USP Butabarbital RS](#) in *Diluent*

Standard solution B: 0.4 mg/mL of [USP Butabarbital RS](#) from *Standard solution A* in *Diluent*

Sample solution: 44 mg/mL of Butabarbital Sodium in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Acetone, methylene chloride, methanol, and ammonium hydroxide (5:3:1:1)

Spray reagent: A solution of mercurous nitrate dihydrate in 0.15 N nitric acid (1 in 100)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, and dry under a current of air. Spray the plate with *Spray reagent*, and immediately estimate the intensities of any spots of the *Sample solution*, other than the principal spot, in comparison with *Standard solution B*.

Acceptance criteria: The R_f value of the principal spot of the *Sample solution* corresponds to that of *Standard solution A*; and the sum of the intensities of any secondary spots of the *Sample solution* is NMT the intensity of the principal spot produced by *Standard solution B*, corresponding to NMT a total of 1% of impurities.

SPECIFIC TESTS

• COMPLETENESS OF SOLUTION

Sample solution: Dissolve 1.0 g of Butabarbital Sodium in 10 mL of carbon dioxide-free water.

Acceptance criteria: After 1 min, the solution is clear and free from undissolved solid.

• pH (791)

Sample solution: Use the *Sample solution* from the test for *Completeness of Solution*.

Acceptance criteria: 10.0–11.2

• LOSS ON DRYING (731)

Analysis: Dry at 150° to constant weight.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in tight containers.

• USP REFERENCE STANDARDS (11)

[USP Butabarbital RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BUTABARBITAL SODIUM	Documentary Standards Support	SM42020 Small Molecules 4
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