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Butabarbital Sodium Tablets

DEFINITION
Butabarbital Sodium Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of butabarbital sodium ($C_{10}H_{15}N_2NaO_3$).

IDENTIFICATION
• **A.** The retention time of the butabarbital peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Solution A: Ammonium hydroxide in water (1 in 25)

Internal standard solution: 1.2 mg/mL of secobarbital in chloroform

Standard solution: 0.8 mg/mL of USP Butabarbital RS and 1 mg/mL of secobarbital in chloroform

Sample stock solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of butabarbital sodium, to a 50-mL volumetric flask. Add 35 mL of *Solution A*, and dilute with water to volume. Filter, if necessary, discarding the first 15 mL of the filtrate, and transfer 25.0 mL of the clear solution to a separator. Add 2 mL of hydrochloric acid, and extract with three 25-mL portions of chloroform. Filter the extracts through about 15 g of anhydrous sodium sulfate that is supported on a funnel by a small pledget of glass wool. Collect the combined filtrate in a 100-mL volumetric flask, and wash the sodium sulfate with 15 mL of chloroform, collecting the washing with the filtrate. Dilute with chloroform to volume.

Sample solution: Combine 4.0 mL of *Sample stock solution* with 1.0 mL of *Internal standard solution* in a suitable container. Reduce the volume to about 1 mL by evaporation, with the aid of a stream of nitrogen, at room temperature.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability.*)

Mode: GC

Detector: Flame ionization

Column: 4-mm × 0.9-m glass; packed with 3% liquid phase G10 support on 80- to 10-mesh S1A

Temperatures

Injection port: 225°

Detector: 225°

Column: 200 ± 10°

Carrier gas: A suitable gas such as dry nitrogen

Flow rate: 60–80 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for butabarbital and secobarbital are 0.6 and 1.0, respectively.]

Resolution: NLT 2.4 between butabarbital and secobarbital

Tailing factor: NMT 2.0 each for butabarbital and secobarbital

Relative standard deviation: NMT 1.5% for the peak response ratio of butabarbital to the internal standard

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

R_U = peak response ratio of butabarbital to the internal standard from the *Sample solution*

R_S = peak response ratio of butabarbital to the internal standard from the *Standard solution*

C_S = concentration of USP Butabarbital RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of butabarbital sodium in the *Sample solution* (mg/mL)

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

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M_{r2} = molecular weight of butabarbital, 212.25

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: USP Butabarbital RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter, and mix with sufficient ammonium hydroxide to provide a concentration of 0.5 N ammonium hydroxide. Dilute with *Medium*, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 239 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of butabarbital sodium ($C_{10}H_{15}N_2NaO_3$) dissolved:

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

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* (mg/mL)

C_U = nominal concentration of butabarbital sodium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

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

M_{r2} = molecular weight of butabarbital, 212.25

Tolerances: NLT 75% (Q) of the labeled amount of butabarbital sodium ($C_{10}H_{15}N_2NaO_3$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.

• **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 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

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