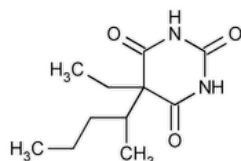


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Pentobarbital

Change to read:



$C_{11}H_{18}N_2O_3$ ▲226.28▲ (USP 1-Aug-2024)

2,4,6(1*H*,3*H*,5*H*)-Pyrimidinetrione, 5-ethyl-5-(1-methylbutyl)-, (±);
 (±)-5-Ethyl-5-(1-methylbutyl)barbituric acid;

▲(R*S*)-5-Ethyl-5-(pentan-2-yl)pyrimidine-2,4,6(1*H*,3*H*,5*H*)-trione▲ (USP 1-Aug-2024) CAS RN®: 76-74-4; UNII: I4744080IR.

DEFINITION

Pentobarbital contains NLT 98.0% and NMT 102.0% of pentobarbital ($C_{11}H_{18}N_2O_3$), calculated on the dried basis. Where the material is labeled as intended solely for veterinary use, Pentobarbital contains NLT 97.0% and NMT 102.0% of pentobarbital ($C_{11}H_{18}N_2O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** ▲197A▲ (USP 1-Aug-2024)

▲▲ (USP 1-Aug-2024)

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#) and 0.01 M [monobasic potassium phosphate](#) (35:65). Adjust ▲ with 25% (v/v) [phosphoric acid](#) solution to a pH of 3.5▲ (USP 1-Aug-2024) ·

Standard solution: 0.1 mg/mL of [USP Pentobarbital RS](#) in *Mobile phase*

▲▲ (USP 1-Aug-2024)

Sample solution: ▲0.1 mg/mL of Pentobarbital in *Mobile phase*. Sonicate to dissolve if necessary.▲ (USP 1-Aug-2024)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

▲**Run time:** NLT 1.8 times the retention time of pentobarbital▲ (USP 1-Aug-2024)

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-Aug-2024)

Tailing factor: NMT 1.5

Relative standard deviation: NMT $\blacktriangle$ 0.73% $\blacktriangle$ (USP 1-Aug-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pentobarbital ($C_{11}H_{18}N_2O_3$) in the portion of Pentobarbital taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak $\blacktriangle$ response of pentobarbital $\blacktriangle$ (USP 1-Aug-2024) from the *Sample solution*

r_S = peak $\blacktriangle$ response of pentobarbital $\blacktriangle$ (USP 1-Aug-2024) from the *Standard solution*

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

C_U = concentration of Pentobarbital in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% $\blacktriangle$ (USP 1-Aug-2024) on the dried basis; and 97.0%–102.0% $\blacktriangle$ (USP 1-Aug-2024) on the dried basis, where the material is labeled as intended solely for veterinary use

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

• ORGANIC IMPURITIES

Mobile phase: Prepare as directed in the Assay.

Standard solution: 0.001 mg/mL of [USP Pentobarbital RS](#) in *Mobile phase*

$\blacktriangle$ Sensitivity solution: 0.0005 mg/mL of [USP Pentobarbital RS](#) from the *Standard solution*, in *Mobile phase* $\blacktriangle$ (USP 1-Aug-2024)

Sample solution: 1 mg/mL of Pentobarbital in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μ L

$\blacktriangle$ Run time: NLT 2.0 times the retention time of pentobarbital $\blacktriangle$ (USP 1-Aug-2024)

System suitability

Samples: *Standard solution* $\blacktriangle$ and *Sensitivity solution*

[NOTE—The relative retention times in [Table 1](#) are provided as information that could aid in peak assignment.]

Table 1 $\blacktriangle$ (USP 1-Aug-2024)

Name	Relative Retention Time
$\blacktriangle$ Pentobarbital imino analog ^a $\blacktriangle$ (USP 1-Aug-2024)	0.39
$\blacktriangle$ Pentobarbital ethyl analog ^b $\blacktriangle$ (USP 1-Aug-2024)	0.93
Pentobarbital	1.0
$\blacktriangle$ Pentobarbital isopropyl analog ^c $\blacktriangle$ (USP 1-Aug-2024)	1.5

^a 6-Imino-5-ethyl-5-(1-methylbutyl)barbituric acid.