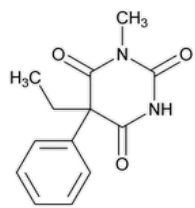


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Mephobarbital



$C_{13}H_{14}N_2O_3$ 246.26
2,4,6-(1*H*,3*H*,5*H*)-Pyrimidinetrione, 5-ethyl-1-methyl-5-phenyl-;
5-Ethyl-1-methyl-5-phenylbarbituric acid CAS RN®: 115-38-8; UNII: 5NC67NU76B.

DEFINITION
Mephobarbital contains NLT 98.0% and NMT 100.5% of mephobarbital ($C_{13}H_{14}N_2O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M▲](#) (CN 1-MAY-2020)
- **B.**
Sample: 200 mg of Mephobarbital
Analysis: Boil the *Sample* with 10 mL of 1 N sodium hydroxide.
Acceptance criteria: Ammonia is evolved.
- **C.**
Diluent: Sodium hydroxide solution (1 in 500)
Sample solution: 12 mg/mL of Mephobarbital prepared as follows. Shake about 60 mg of Mephobarbital with 5 mL of *Diluent*, and filter. Use the filtrate.
Analysis 1: Add 3 drops of mercuric nitrate TS to 1 mL of the *Sample solution*.
Acceptance criteria 1: A white precipitate is formed, and it is soluble in 6 N ammonium hydroxide.
Analysis 2: Add silver nitrate TS to 1 mL of the *Sample solution*.
Acceptance criteria 2: A white precipitate is formed, and it dissolves readily in 6 N ammonium hydroxide.

ASSAY

- **PROCEDURE**
Sample solution: 10 mg/mL of Mephobarbital in dimethylformamide
Analysis: Transfer 50 mL of *Sample solution* to a 200-mL flask. Add 4 drops of thymolphthalein TS. Titrate with 0.1 N lithium methoxide in toluene VS using a magnetic stirrer and a cover for the flask to protect against atmospheric carbon dioxide. Perform a blank determination. Each mL of 0.1 N lithium methoxide is equivalent to 24.63 mg of mephobarbital ($C_{13}H_{14}N_2O_3$).
Acceptance criteria: 98.0%–100.5% on the dried basis

IMPURITIES

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

SPECIFIC TESTS

- [LOSS ON DRYING \(731\)](#)
Analysis: Dry a sample at 105° for 4 h.
Acceptance criteria: NMT 1.0%
- **MELTING RANGE OR TEMPERATURE, [Class I \(741\)](#):** 176°–181°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS (11).**
[USP Mephobarbital RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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