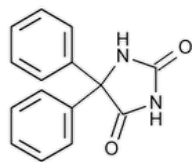


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Phenytoin



$C_{15}H_{12}N_2O_2$ 252.27
2,4-Imidazolidinedione, 5,5-diphenyl-;
5,5-Diphenylhydantoin CAS RN®: 57-41-0; UNII: 6158TKW0C5.

DEFINITION
Phenytoin contains NLT 98.0% and NMT 102.0% of phenytoin ($C_{15}H_{12}N_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **PROCEDURE**

Solution A: Prepare a 0.05 M monobasic potassium phosphate solution and adjust with phosphoric acid to a pH of 2.5.
Solution B: Methanol and acetonitrile (60:40)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
23	60	40
38	42	58
45	30	70
50	30	70
51	60	40
55	60	40

Diluent: *Solution B* and water (1:1)
Standard solution: 0.2 mg/mL of [USP Phenytoin RS](#) in *Diluent*. Dissolve with the aid of sonication if necessary.
Sample solution: 0.2 mg/mL of Phenytoin in *Diluent*. Dissolve with the aid of sonication if necessary.
Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 3-μm packing L1

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenytoin ($C_{15}H_{12}N_2O_2$) in the portion of Phenytoin taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 1 μg/mL of [USP Phenytoin RS](#), 5 μg/mL of [USP Phenytoin Related Compound A RS](#), 9 μg/mL of [USP Phenytoin Related Compound B RS](#), and 1 μg/mL of [USP Benzophenone RS](#) in *Diluent*

Sample solution: 1 mg/mL of Phenytoin in *Diluent*

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times are given in [Table 2](#).]

Suitability requirements

Signal-to-noise ratio: NLT 10

Relative standard deviation: NMT 5.0% for the phenytoin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each specified impurity in the portion of Phenytoin taken:

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

r_U = peak area of specified impurity from the *Sample solution*

r_S = peak area of corresponding impurity from the *Standard solution*

C_S = concentration of corresponding impurity in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Phenytoin taken:

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

r_U = peak area for each unspecified impurity

r_S = peak area of phenytoin from the *Standard solution*