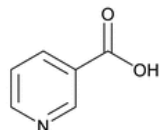


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Niacin



$C_6H_5NO_2$ 123.11

3-Pyridinecarboxylic acid;

Nicotinic acid CAS RN®: 59-67-6; UNII: 2679MF687A.

DEFINITION

Niacin contains NLT 98.0% and NMT 102.0% of niacin ($C_6H_5NO_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Change to read:

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

Wavelength range: 200–300 nm

Buffer solution: Dissolve 6.8 g of [monobasic potassium phosphate](#) in 1000 mL of water. Adjust with 50% sodium hydroxide solution to a pH of 7.0.

Sample solution: 20 µg/mL in *Buffer solution*

Acceptance criteria: Meets the requirements. The A_{239}/A_{263} ratio is 0.46–0.52.

- C. 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

Diluent: Methanol and water (82:18)

Mobile phase: Methanol and water (82:18), adjusted with [glacial acetic acid](#) to a pH of 3.15 ± 0.05

System suitability solution: 0.25 mg/mL of [USP Niacin RS](#), 0.050 mg/mL of [USP 6-Hydroxynicotinic Acid RS](#), and 0.10 mg/mL of pyridine in *Diluent*

Standard solution: 0.25 mg/mL of [USP Niacin RS](#) in *Diluent*

Sample solution: 0.25 mg/mL of Niacin in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L8](#)

Flow rate: 1.0 mL/min

Injection volume: 25 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for pyridine, 6-hydroxynicotinic acid, and niacin are about 0.14, 0.64, and 1.0, respectively, *System suitability solution*.]

Suitability requirements

Resolution: NLT 1.5 between pyridine and 6-hydroxynicotinic acid and NLT 1.5 between 6-hydroxynicotinic acid and niacin, *System suitability solution*

Relative standard deviation: NMT 2.0% for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of niacin ($C_6H_5NO_2$) in the portion of Niacin taken:

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

r_U = peak response of niacin from the *Sample solution*

r_S = peak response of niacin from the *Standard solution*

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

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

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

IMPURITIES

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

• [CHLORIDE AND SULFATE, Chloride \(221\)](#)

Standard: 0.15 mL of 0.020 N hydrochloric acid

Sample: 0.50 g of Niacin

Acceptance criteria: NMT 0.02%

• [CHLORIDE AND SULFATE, Sulfate \(221\)](#)

Standard: 0.10 mL of 0.020 N sulfuric acid

Sample: 0.50 g of Niacin

Acceptance criteria: NMT 0.02%

RELATED COMPOUNDS

Solution A: Dissolve 0.6 g of [glacial acetic acid](#) in 1 L of water, and adjust with 10% [ammonium hydroxide](#) solution to a pH of 5.6.

Solution B: Acetonitrile and methanol (1:1)

Mobile phase: Gradient elution. See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
10 ^a	100	0
30	20	80
35	20	80
36	100	0
48	100	0

^a The gradient start time may be adjusted to achieve the required resolution between the 6-methylnicotinic acid and 6,6'-dinicotinic acid peaks of the *System suitability solution*.

System suitability solution: Transfer 3 mg each of [USP 6-Methylnicotinic Acid RS](#), USP 6,6'-Dinicotinic Acid RS, and pyridine to a 100-mL volumetric flask, dissolve, and dilute with *Solution A* to volume. Transfer 2.0 mL of the resultant solution to a 5-mL volumetric flask, and dilute with *Solution A* to volume.

Standard solution: 0.012 mg/mL of [USP Niacin RS](#) in *Solution A*