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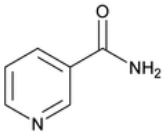
Niacinamide



$C_6H_6N_2O$ 122.12
3-Pyridinecarboxamide;
Nicotinamide CAS RN®: 98-92-0; UNII: 25X51I8RD4.

DEFINITION
Niacinamide contains NLT 98.5% and NMT 101.5% of niacinamide ($C_6H_6N_2O$), calculated on the dried basis.

IDENTIFICATION
Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Change to read:

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**▲ (CN 1-May-2020)

Sample solution: 20 µg/mL in water
Acceptance criteria: It meets the requirements in the chapter, and the A_{245}/A_{262} ratio is 0.63–0.67.

ASSAY
• **Procedure**

Mobile phase: Methanol and 0.005 M sodium 1-heptanesulfonate (30:70)
Standard solution: Transfer 50 mg of USP Niacinamide RS to a 100-mL volumetric flask. Add 3 mL of water to dissolve, and dilute with *Mobile phase* to volume. Dilute with *Mobile phase* to 0.04 mg/mL.
Niacin standard solution Prepare as directed in the *Standard solution*, using USP Niacin RS instead of USP Niacinamide RS.
Sample solution: Prepare as directed in the *Standard solution*, using Niacinamide instead of USP Niacinamide RS.
System suitability solution: Mix equal volumes of the *Standard solution* and *Niacin standard solution*.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 3.9-mm × 30-cm; packing L1
Flow rate: 2 mL/min
Injection size: 20 µL
System suitability
Samples: *Standard solution* and *System suitability solution*
Suitability requirements
Resolution: NLT 3.0 between niacin and niacinamide, *System suitability solution*
Relative standard deviation: NMT 2.0%, *Standard solution*
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of niacinamide ($C_6H_6N_2O$) in the portion of Niacinamide taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Readily Carbonizable Substances ⟨271⟩**

  Sample solution: Dissolve 200 mg of Niacinamide in 5 mL of sulfuric acid.

  Acceptance criteria: The *Sample solution* has no more color than *Matching Fluid A*.

SPECIFIC TESTS

- **Melting Range or Temperature ⟨741⟩:** 128°–131°
- **Loss on Drying ⟨731⟩:** Dry a sample over silica gel for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards ⟨11⟩**

  USP Niacin RS

  USP Niacinamide RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NIACINAMIDE	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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