Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-71927FC8-D4E5-4B7C-802F-552AC3058EEB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M56590_02_01
DOI Ref: c7xvc

Niacinamide Tablets

DEFINITION

Niacinamide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of niacinamide ($C_6H_6N_2O$).

IDENTIFICATION

Change to read:

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

Sample: Extract a quantity of powdered Tablets, equivalent to 500 mg of niacinamide, with two 10-mL portions of alcohol, evaporate the filtered alcohol extracts on a steam bath, and dry at 80° for 2 h.

Acceptance criteria: Meet the requirements

Change to read:

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

Sample solution: 20 µg/mL of niacinamide in water from the *Sample* obtained in *Identification* test *A*

Acceptance criteria: Meets the requirements in the chapter. The ratio A_{245}/A_{262} is 0.63–0.67.

ASSAY

• **Niacin or Niacinamide Assay, *Chemical Method*⟨441⟩**

Standard niacinamide preparation: Prepare as directed in the chapter.

Assay preparation: Transfer an equivalent of 25 mg of niacinamide, from NLT 10 finely powdered Tablets, to a suitable flask. Add 50 mL of water and heat, if necessary, until no more dissolves. Cool, dilute with water to 10 µg/mL, mix, and filter.

Analysis: Proceed as directed in the chapter for *Procedure*.

Calculate the percentage of the labeled amount of niacinamide ($C_6H_6N_2O$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Assay preparation*

A_S = absorbance of the *Standard niacinamide preparation*

C_S = concentration of the *Standard niacinamide preparation* (µg/mL)

C_U = nominal concentration of niacinamide in the *Assay preparation* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution, *Procedure for a Pooled Sample*⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: Known concentration of USP Niacinamide RS in the *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

Mobile phase: A mixture of methanol, glacial acetic acid, and water (27:1:73) containing 140 mg of sodium 1-hexanesulfonate per 100 mL

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of niacinamide ($C_6H_6N_2O$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D \times V/L) \times 100$$

r_U = peak area of niacinamide from the *Sample solution*

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

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

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of niacinamide ($C_6H_6N_2O$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Niacinamide RS

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

Topic/Question	Contact	Expert Committee
NIACINAMIDE TABLETS	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 30(1)

Current DocID: GUID-71927FC8-D4E5-4B7C-802F-552AC3058EEB_2_en-US

DOI: https://doi.org/10.31003/USPNF_M56590_02_01

DOI ref: c7xvc