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Niacin Tablets

DEFINITION

Niacin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of niacin ($C_6H_5NO_2$).

IDENTIFICATION

Change to read:

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

Sample: Heat a portion of finely powdered Tablets, equivalent to 500 mg of niacin, with 25 mL of alcohol on a steam bath for a few min. Filter, and wash the residue with a few mL of hot alcohol. To the filtrate add 30 mL of water, and evaporate to 25 mL on the steam bath. Cool, filter if insoluble matter separates, and evaporate the filtrate to 10 mL. Cool, and place in a refrigerator for 1 h. Filter the separated niacin with suction, wash it with a few mL of cold alcohol, and dry at 105° for 1 h.

Acceptance criteria: Meet the requirements

Change to read:

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

Medium: 6.8 mg/mL of monobasic potassium phosphate in water, adjusted to a pH of 7.0 with 50% sodium hydroxide solution

Sample solution: 20 µg/mL in *Medium* from the *Sample* obtained in the *Identification* test *A*

Acceptance criteria: Meets the requirements in the chapter. The A_{237}/A_{262} ratio is 0.46–0.50.

• **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**

Solution A: 5-mM solution of sodium 1-hexanesulfonate in water

Mobile phase: Methanol, acetonitrile, glacial acetic acid, and *Solution A* (14:7:1:78)

Standard solution: 0.050 mg/mL of USP Niacin RS in water. Dissolve with the aid of heat in a steam bath.

Sample solution: Transfer an equivalent to 500 mg of Niacin from NLT 20 finely powdered Tablets to a suitable flask. Add 50 mL of water, and heat on a steam bath for 30 min. Sonicate for 2 min, shake by mechanical means for 15 min, and cool to room temperature. Dilute with water to 0.050 mg/mL, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 262 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.3 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates for the analyte peak

Tailing factor: NMT 2.0 for the analyte peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of niacin ($C_6H_5NO_2$) in the portion of Tablets 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 Niacin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 60 min

Standard solution: 0.02 mg/mL of USP Niacin RS in the *Medium*

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

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: Maximum at about 260 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the concentration of niacin in the *Sample solution* in comparison with the *Standard solution*.

Calculate the percentage of the labeled amount of niacin ($C_6H_5NO_2$) dissolved:

$$\text{Result} = (C \times D \times V/L) \times 100$$

C = determined concentration of niacin in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 65% (Q) of the labeled amount of niacin ($C_6H_5NO_2$) is dissolved.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Niacin RS

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

Topic/Question	Contact	Expert Committee
NIACIN 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. Information currently unavailable

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