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Isoniazid Tablets

DEFINITION

Isoniazid Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of isoniazid ($C_6H_7N_3O$).

IDENTIFICATION

• **A.** The retention time of the isoniazid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

• **B. ULTRAVIOLET ABSORPTION**

Sample stock solution: Nominally 0.1 mg/mL of isoniazid in water prepared from a portion of finely powdered Tablets

Sample solution: Nominally 0.01 mg/mL of isoniazid in water prepared as follows. Transfer 10.0 mL of *Sample stock solution* to a 100-mL volumetric flask, add 2.0 mL of 0.1 N hydrochloric acid, and dilute with water to volume.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima only at the same wavelengths as that of a similar solution of [USP Isoniazid RS](#), concomitantly measured.

ASSAY

• **PROCEDURE**

Buffer: To 0.1 M monobasic potassium phosphate solution, adjusted with 10 N sodium hydroxide to a pH of 6.9, add sufficient triethanolamine to obtain a solution of 0.2 mM of triethanolamine.

Mobile phase: *Buffer* and methanol (95:5)

Standard solution: 0.32 mg/mL of [USP Isoniazid RS](#) in *Mobile phase*

Sample solution: Nominally 0.32 mg/mL of isoniazid in *Mobile phase* prepared as follows. Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 32 mg of isoniazid, to a 100-mL volumetric flask. Add 40 mL of *Mobile phase*, and sonicate for 10 min. Cool to room temperature, dilute with *Mobile phase* to volume, and centrifuge for 5 min.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, k' : NLT 2.35

Column efficiency: NLT 1800 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of isoniazid ($C_6H_7N_3O$) in the portion of Tablets 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 Isoniazid RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Detector: UV 263 nm

Standard solution: [USP Isoniazid RS](#) in *Medium*

Sample solution: Dilute with *Medium* to a nominal concentration that is similar to that of the *Standard solution*.

Analysis: Determine the percentage of the labeled amount of isoniazid ($C_6H_7N_3O$) dissolved by using UV absorption on filtered portions of the solution under test, suitably diluted with *Medium*, in comparison with the *Standard solution*.

Tolerances: NLT 80% (Q) of the labeled amount of isoniazid ($C_6H_7N_3O$) is dissolved.

Change to read:

- **UNIFORMITY OF DOSAGE UNITS (905):** ▲ Meet the requirements ▲ (CN 1-Aug-2023)

Procedure for content uniformity

Diluent: 0.1 N hydrochloric acid and water (3 in 100)

Standard solution: 10 µg/mL of [USP Isoniazid RS](#) prepared as follows. Dissolve a quantity of [USP Isoniazid RS](#) in a volume of water corresponding to that used to dissolve a similar amount of isoniazid from the Tablet, and dilute with *Diluent*.

Sample solution: Nominally 10 µg/mL of isoniazid prepared as follows. Transfer 1 finely powdered Tablet to a 500-mL volumetric flask with the aid of 200 mL of water. Shake by mechanical means for 30 min, and add water to volume. Filter, and discard the first 20 mL of the filtrate. Dilute a portion of the filtrate with *Diluent*.

Instrumental conditions

Mode: UV

Analytical wavelength: 263 nm

Cell: 1 cm

Blank: Water

Calculate the percentage of the labeled amount of isoniazid ($C_6H_7N_3O$) in the Tablet taken:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = nominal concentration of isoniazid in the *Sample solution* (µg/mL)

▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.
- **USP REFERENCE STANDARDS (11):**
[USP Isoniazid RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ISONIAZID TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 46(2)

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