Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-EDD8F7A2-D1A0-4AC5-AFCD-D968CF66071B_3_en-US
DOI: https://doi.org/10.31003/USPNF_M42990_03_01
DOI Ref: t0b4t

Isoniazid Injection

DEFINITION

Isoniazid Injection is a sterile solution of Isoniazid in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of isoniazid ($C_6H_7N_3O$).

IDENTIFICATION

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

• **B.**

Sample stock solution: Nominally 0.1 mg/mL of isoniazid in water prepared as follows. Transfer an equivalent to 50 mg of isoniazid from a volume of Injection to a 500-mL volumetric flask, and dilute with water to volume.

Sample solution: 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**

Mobile phase: 4.4 g/L of docusate sodium in a mixture of methanol and water (600:400), and adjust with 2 N sulfuric acid to a pH of 2.5.

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*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1800 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

r_S = peak response of isoniazid 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%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 6.0–7.0
- **Bacterial Endotoxins Test** ⟨85⟩**:** Contains NMT 0.3 USP Endotoxin Unit/mg of isoniazid
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.
- **Labeling:** Its package label states that if crystallization has occurred, the Injection should be warmed to redissolve the crystals before use.
- **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 INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-EDD8F7A2-D1A0-4AC5-AFCD-D968CF66071B_3_en-US
Previous DocID: GUID-EDD8F7A2-D1A0-4AC5-AFCD-D968CF66071B_1_en-US
DOI: https://doi.org/10.31003/USPNF_M42990_03_01
DOI ref: t0b4t