

Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocID: GUID-3E2EB6E3-DFAB-45A0-9400-B45CEAACB698_1_en-US
DOI: https://doi.org/10.31003/USPNF_M43000_01_01
DOI Ref: u2t59

© 2025 USPC
Do not distribute

Isoniazid Oral Solution

DEFINITION

Isoniazid Oral Solution contains, in each 100 mL, NLT 0.93 g and NMT 1.10 g of isoniazid ($C_6H_7N_3O$).

IDENTIFICATION

• A.

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 Oral Solution 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

• [NITRITE TITRATION \(451\)](#).

Diluent: Dilute hydrochloric acid (1 in 6)

Sample solution: Nominally 2 mg/mL of isoniazid prepared as follows. To a volume of Oral Solution, equivalent to 100 mg of isoniazid, add 50 mL of a mixture of 1 part of potassium bromide in 10 parts of *Diluent*.

Analysis: Proceed as directed in the chapter, beginning with "cool to about 15°". Each mL of 0.1 M sodium nitrite is equivalent to 13.71 mg of isoniazid ($C_6H_7N_3O$).

Acceptance criteria: 0.93–1.10 g in each 100 mL

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, 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 ORAL SOLUTION	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. PF 28(2)

Current DocID: GUID-3E2EB6E3-DFAB-45A0-9400-B45CEAACB698_1_en-US

DOI: https://doi.org/10.31003/USPNF_M43000_01_01

DOI ref: [u2t59](#)