

$C_6H_7N_3O$: 137.14

Pyridine-4-carbohydrazide [54-85-3]

Isoniazid, when dried, contains not less than 98.5% of $C_6H_7N_3O$.

Description Isoniazid occurs as colorless crystals or a white, crystalline powder. It is odorless.

It is freely soluble in water, sparingly soluble in ethanol (95), slightly soluble in acetic anhydride, and very slightly soluble in diethyl ether.

Identification (1) Dissolve about 0.02 g of Isoniazid in water to make 200 mL. To 5 mL of the solution add 1 mL of 0.1 mol/L hydrochloric acid TS and water to make 50 mL. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Isoniazid, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

pH Dissolve 1.0 g of Isoniazid in 10 mL of freshly boiled and cooled water: the pH of this solution is between 6.5 and 7.5.

Melting point 170 – 173°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of isoniazid in 20 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Isoniazid according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 0.40 g of Isoniazid according to Method 3, and perform the test using Apparatus B. In this case, add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 50), then add 1.5 mL of hydrogen peroxide (30), and ignite the ethanol to burn (not more than 5 ppm).

(4) Hydrazine—Dissolve 0.10 g of isoniazid in 5 mL of water, add 0.1 mL of a solution of salicylaldehyde in ethanol (95) (1 in 20), shake immediately, and allow to stand for 5 minutes: no turbidity is produced.

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.3 g of isoniazid, previously dried, dissolve in 50 mL of acetic acid (100) and 10 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from yellow to green (indicator: 0.5 mL of *p*-naphtholbenzein TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 13.714 mg of $C_6H_7N_3O$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Isoniazid Injection

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Isoniazid Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of isoniazid ($C_6H_7N_3O$: 137.14).

Method of preparation Prepare as directed under Injections, with Isoniazid.

Description Isoniazid Injection occurs as a clear, colorless liquid. It has a slight, bitter taste.

pH: 6.5 – 7.5

Identification (1) To a volume of Isoniazid Injection, equivalent to 0.01 g of Isoniazid according to the labeled amount, and add water to make 2 mL. Add 1 mL of silver nitrate-ammonia TS to this solution: a dark turbidity is produced, and a silver mirror is formed on the wall of the test tube with effervescence.

(2) To a volume of Isoniazid Injection, equivalent to 0.1 g of Isoniazid according to the labeled amount, add water to make 4 mL. Add 0.1 g of vanillin and 4 mL of ethanol (95), dissolve by warming moderately, and allow to stand for 3 hours. Collect the precipitated yellow crystals by filtration, and dry at 105°C for 1 hour: the crystals melt between 225°C and 231°C.

Assay To an exactly measured volume of Isoniazid Injection, equivalent to about 0.025 g of isoniazid ($C_6H_7N_3O$), add water to make exactly 250 mL. Pipet 10 mL of the solution, add 10 mL of 1 mol/L hydrochloric acid TS and water to make exactly 100 mL, and use this solution as the sample solution. Dry isoniazid for assay at 105°C for 2 hours, weigh accurately about 0.025 g of the residue, and dissolve in water to make exactly 250 mL. Pipet 10 mL of the solution, add 10 mL of 1 mol/L hydrochloric acid TS and water to make exactly 100 mL, and use this solution as the standard solution. Perform the test as directed under the Ultraviolet-visible Spectrophotometry, and determine the absorbances, A_T and A_S , of the sample solution and the standard solution at the wavelength of 267 nm, respectively.

Amount (mg) of isoniazid ($C_6H_7N_3O$)

$$= \text{amount (mg) of isoniazid for assay} \times \frac{A_T}{A_S}$$

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Isoniazid Tablets

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Isoniazid Tablets contain not less than 95% and not more than 105% of the labeled amount of isoniazid ($C_6H_7N_3O$: 137.14).

Method of preparation Prepare as directed under Tablets, with Isoniazid.