Identification Take a quantity of powdered Isoniazid Tablets, equivalent to 0.02 g of Isoniazid according to the labeled amount, add 200 mL of water, shake well, and filter. To 5 mL of the filtrate add 1 mL of 0.1 mol/L hydrochloric acid TS and water to make 50 mL, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 264 nm and 268 nm.

Dissolution test Perform the test with 1 tablet of Isoniazid Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of water as the test solution. Take 20 mL or more of the dissolved solution 20 minutes after starting the test, and filter through a membrane filter with pore size of not more than 0.45 μm. Discard the first 10 mL of the filtrate, pipet 5 mL of the subsequent, add water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.10 g of isoniazid for assay, previously dried at 105°C for 2 hours, dissolve in water to make exactly 100 mL, then pipet 5 mL of this solution, add water to make exactly 50 mL, and then pipet 5 mL of this solution, add water to make exactly 50 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 267 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Isoniazid Tablets in 20 minutes is not less than 75%.

Dissolution rate (%) with respect to the labeled amount of isoniazid ($C_6H_7N_3O$)

$$= W_S \times \frac{A_T}{A_S} \times \frac{90}{C}$$

W_S: Amount (mg) of isoniazid for assay.
C: Labeled amount (mg) of isoniazid ($C_6H_7N_3O$) in 1 tablet.

Assay Weigh accurately and powder not less than 20 Isoniazid Tablets. Weigh accurately a quantity of the powder, equivalent to about 0.10 g of isoniazid ($C_6H_7N_3O$), add 150 mL of water, shake for 30 minutes, then add water to make exactly 200 mL, and filter. Discard the first 10 mL of the filtrate, pipet 5 mL of the subsequent filtrate, add the mobile phase to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of isoniazid for assay, previously dried at 105°C for 2 hours, dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add the mobile phase to make exactly 50 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following operating conditions. Determine the peak areas, A_T and A_S, of isoniazid of the sample solution and the standard solution.

Amount (mg) of $C_6H_7N_3O$

$$= \text{amount (mg) of isoniazid for assay} \times \frac{A_T}{A_S} \times 2$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 265 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 6.80 g of potassium dihydrogenphosphate in water to make 1000 mL. Separately, to 5.76 g of phosphoric acid add water to make 1000 mL. Mix these solutions to adjust the pH to 2.5. To 400 mL of this solution add 600 mL of methanol, and dissolve 2.86 g of sodium tridecanesulfonate in this.

Flow rate: Adjust the flow rate so that the retention time of isoniazid is about 5 minutes.

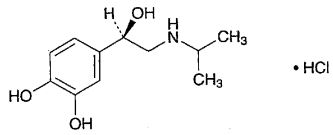
Selection of column: Dissolve 5 mg of Isoniazid and 5 mg of isonicotinic acid in 100 mL of the mobile phase. Proceed with 10 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of isonicotinic acid and isoniazid in this order with the resolution between these peaks being not less than 1.5.

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

l-Isoprenaline Hydrochloride

l-Isoproterenol Hydrochloride

l-塩酸イソプレナリン



$C_{11}H_{17}NO_3.HCl$: 247.72
(1*R*)-1-(3,4-Dihydroxyphenyl)-2-(isopropylamino)ethanol monohydrochloride [*51-30-9*]

l-Isoprenaline Hydrochloride, when dried, contains not less than 98.0% of $C_{11}H_{17}NO_3.HCl$.

Description *l*-Isoprenaline Hydrochloride occurs as a white, crystalline powder. It is odorless.

It is freely soluble in water, sparingly soluble in ethanol (95), and practically insoluble in acetic acid (100), in acetic anhydride, in diethyl ether and in chloroform.

It gradually changes in color by air and by light.

Identification **(1)** Dissolve 0.01 g of *l*-Isoprenaline Hydrochloride in 5 mL of water, and add 1 drop of iron (III) chloride TS: a deep green color develops, and changes through yellow-green to brown on standing.

(2) Dissolve 1 mg each of *l*-Isoprenaline Hydrochloride in 1 mL of water in the test tubes A and B. Add 10 mL of potassium hydrogen phthalate buffer solution, pH 3.5 to A, and add 10 mL of phosphate buffer solution, pH 6.5 to B. To each of the test tubes add 1 mL of iodine TS, allow to stand for 5 minutes, and add 2 mL each of sodium thiosulfate TS: a red color develops in the test tube A, and a deep red color develops in the test tube B.

(3) Dissolve 0.01 g of *l*-Isoprenaline Hydrochloride in 1 mL of water, and add 1 mL of phosphotungstic acid TS: a light brown precipitate is produced.

(4) Determine the absorption spectrum of a solution of *l*-Isoprenaline Hydrochloride in 0.1 mol/L hydrochloric acid TS (1 in 20,000) 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.

(5) A solution of *l*-Isoprenaline Hydrochloride (1 in 10) responds to the Qualitative Tests (2) for chloride.

Optical rotation $[\alpha]_D^{20}$: -36 - $-41°$ (after drying, 0.25 g, water, 25 mL, 100 mm).

pH Dissolve 0.01 g of *l*-Isoprenaline Hydrochloride in 10 mL of water: the pH of the solution is between 4.5 and 5.5.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of *l*-Isoprenaline Hydrochloride in 20 mL of 0.1 mol/L hydrochloric acid TS: the solution is clear and colorless.

(2) Sulfate—Perform the test with 0.10 g of *l*-Isoprenaline Hydrochloride. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.192%).

(3) Heavy metals—Proceed with 1.0 g of *l*-Isoprenaline Hydrochloride according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(4) Isoproterenone—Dissolve 0.050 g of *l*-Isoprenaline Hydrochloride in 0.01 mol/L hydrochloric acid TS to make exactly 25 mL, and determine the absorbance of the solution at 310 nm: not more than 0.040.

Loss on drying Not more than 0.5% (1 g, in vacuum, silica gel, 4 hours).

Residue on ignition Not more than 0.20% (1 g).

Assay Weigh accurately about 0.5 g of *l*-Isoprenaline Hydrochloride, previously dried, dissolve in 100 mL of a mixture of acetic acid (100) and acetic anhydride (3:2) by warming, cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination.

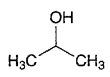
Each mL of 0.1 mol/L perchloric acid VS
= 24.772 mg of $C_{11}H_{17}NO_3.HCl$

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

Isopropanol

Isopropyl Alcohol

イソプロパノール



C_3H_8O: 60.10
Propan-2-ol [*67-63-0*]

Description Isopropanol is a clear, colorless liquid. It has a characteristic odor.

It is miscible with water, with methanol, with ethanol (95), and with diethyl ether.

It is flammable and volatile.

Identification **(1)** To 1 mL of Isopropanol add 2 mL of iodine TS and 2 mL of sodium hydroxide TS, and shake: a light yellow precipitate is formed.

(2) To 5 mL of Isopropanol add 20 mL of potassium dichromate and 5 mL of sulfuric acid with caution, and warm gently on a water bath: the produced gas has the odor of acetone, and the gas turns the filter paper, previously wetted with a solution of salicylaldehyde in ethanol (95) (1 in 10) and with a solution of sodium hydroxide (3 in 10), to red-brown.

Specific gravity d_{20}^{20}: 0.785 - 0.788

Purity **(1)** Clarity of solution—To 2.0 mL of Isopropanol add 8 mL of water, and shake: the solution is clear.

(2) Acid—To 15.0 mL of Isopropanol add 50 mL of freshly boiled and cooled water and 2 drops of phenolphthalein TS, and add 0.40 mL of 0.01 mol/L sodium hydroxide VS: a red color develops.

(3) Residue on evaporation—Evaporate 20.0 mL of Isopropanol on a water bath to dryness, and dry at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Water Not more than 0.75 w/v% (2 mL, direct titration).

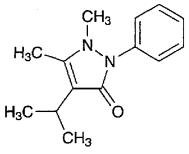
Distilling range 81 - 83°C, not less than 94 vol%.

Containers and storage Containers—Tight containers.
Storage—Remote from fire.

Isopropylantipyrine

Propyphenazone

イソプロピルアンチピリン



$C_{14}H_{18}N_2O$: 230.31
4-Isopropyl-1,5-dimethyl-2-phenyl-1,2-dihydropyrazol-3-one [*479-92-5*]

Isopropylantipyrine, when dried, contains not less than 98.0% of $C_{14}H_{18}N_2O$.

Description Isopropylantipyrine occurs as white crystals or crystalline powder. It is odorless, and has a slightly bitter taste.

It is very soluble in acetic acid (100), freely soluble in ethanol (95) and in acetone, soluble in diethyl ether, and slightly soluble in water.

Identification **(1)** To 2 mL of a solution of Isopropylantipyrine (1 in 500) add 1 drop of iron (III) chloride TS: a light red color develops. Further add 3 drops of sulfuric acid to this solution: the color changes to pale yellow.

(2) Add 5 mL of a solution of Isopropylantipyrine (1 in 500) to a mixture of 5 mL of potassium hexacyanoferrate