

Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thinlayer chromatography. Develop the plate with a mixture of ethyl acetate, hexane, 1-butanol and ammonia solution (28) (140:40:20:1) to a distance of about 10 cm, and air-dry the plate. Spray hydrogen hexachloroplatinate (IV)-potassium iodide TS evenly on the plate: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water Not more than 4.0% (0.5 g, direct titration).

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

Assay Weigh accurately about 0.5 g of Ifenprodil Tartrate, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

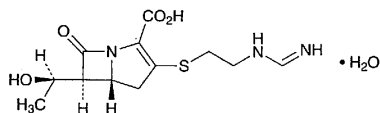
Each mL of 0.1 mol/L perchloric acid VS
= 40.05 mg of $(\text{C}_{21}\text{H}_{27}\text{NO}_2)_2 \cdot \text{C}_4\text{H}_6\text{O}_6$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Imipenem

イミペネム



$\text{C}_{12}\text{H}_{17}\text{N}_3\text{O}_4\text{S} \cdot \text{H}_2\text{O}$: 317.36
(5*R*,6*S*)-3-[2-(Formimidoylamino)ethylsulfanyl]-6-[(1*R*)-1-hydroxyethyl]-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid monohydrate [74431-23-5]

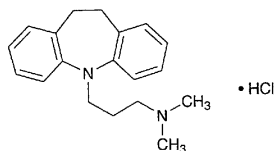
Imipenem conforms to the requirements of Imipenem in the Requirements for Antibiotic Products of Japan.

Description Imipenem occurs as a white to light yellow crystalline powder.

It is sparingly soluble in water, slightly soluble in methanol, and practically insoluble in ethanol (95) and in diethyl ether.

Imipramine Hydrochloride

塩酸イミプラミン



$\text{C}_{19}\text{H}_{24}\text{N}_2 \cdot \text{HCl}$: 316.87

N-[3-(10,11-Dihydro-5*H*-dibenz[*b,f*]azepin-5-yl)propyl]-*N,N*-dimethylamine monohydrochloride [113-52-0]

Imipramine Hydrochloride, when dried, contains not less than 98.5% of $\text{C}_{19}\text{H}_{24}\text{N}_2 \cdot \text{HCl}$.

Description Imipramine Hydrochloride occurs as a white to pale yellowish white, crystalline powder. It is odorless.

It is freely soluble in water and in ethanol (95), and practically insoluble in diethyl ether.

The pH of the aqueous solution (1 in 10) is between 4.2 and 5.2.

It is gradually colored by light.

Identification (1) Dissolve 5 mg of Imipramine Hydrochloride in 2 mL of nitric acid: a deep blue color develops.

(2) Dissolve 5 mg of Imipramine Hydrochloride in 250 mL of 0.01 mol/L hydrochloric acid TS. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Imipramine Hydrochloride Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(3) Dissolve 0.05 g of Imipramine Hydrochloride in 5 mL of water, add 1 mL of ammonia TS, allow to stand for 5 minutes, filter, and acidify the filtrate with dilute nitric acid: it responds to the Qualitative Tests (2) for chloride.

Melting point 170–174°C (with decomposition).

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Imipramine Hydrochloride in 10 mL of water: the solution is clear, and has no more color than the following control solution.

Control solution: Take exactly 1.0 mL of Cobaltous Chloride Colorimetric Stock Solution, 2.4 mL of Ferric Chloride Colorimetric Solution, 0.4 mL of Cupric Sulfate Colorimetric Stock Solution and 6.2 mL of diluted hydrochloric acid (1 in 40), and mix them. Pipet 0.5 mL of this solution, and add exactly 9.5 mL of water.

(2) Iminodibenzyl—Dissolve 0.050 g of Imipramine Hydrochloride in 10 mL of a mixture of hydrochloric acid and ethanol (95) (1:1) in a 25-mL brown volumetric flask. Cool the flask in ice water, add 5 mL of an ethanol (95) solution of furfural (1 in 250) and 5 mL of hydrochloric acid, and allow to stand at 25°C for 3 hours. Add a mixture of hydrochloric acid and ethanol (95) (1:1) to make 25 mL, and determine the absorbance of this solution at 565 nm as directed under the Ultraviolet-visible Spectrophotometry: it is not more than 0.16.

(3) Related substances—Dissolve 0.20 g of Imipramine Hydrochloride in 10 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of this solution, and add ethanol (95) to make exactly 50 mL. Pipet 5 mL of this solution, add ethanol (95) to make exactly 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, acetic acid (100), hydrochloric acid and water