

less than 3 animals are killed.

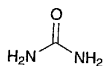
Toxicity Inject intravenously 0.50 mL of Ulinastatin into each of five well-fed, healthy albino mice weighing 18 to 25 g: no mouse dies within 48 hours after injection. If any mouse dies within 48 hours, repeat the test using 5 albino mice weighing 19 to 21 g: all the animals survive for 48 hours.

Assay Measure exactly a suitable volume of Ulinastatin, dilute with 2,2',2''-nitrilotrisethanol buffer solution so that each mL of the solution contains about 150 Units according to the labeled amount, and use this solution as the sample solution. Separately, dilute a suitable volume of Ulinastatin Reference Standard with 2,2',2''-nitrilotrisethanol buffer solution so that each mL of the solution contains exactly 300, 200, 100, 50 or 0 Units, and use these solutions as the standard solutions. 2,2',2''-Nitrilotrisethanol buffer solution and *N*- α -benzoyl-L-arginine-4-nitroanilide TS are warmed in a water bath of $25 \pm 1^\circ\text{C}$ for use as described below. Take exactly 0.1 mL each of the sample solution and the standard solutions in test tubes, add exactly 1.6 mL of 2,2',2''-nitrilotrisethanol buffer solution, mix, and put the tubes in the water bath of $25 \pm 1^\circ\text{C}$. One minute after addition of the buffer solution add exactly 0.2 mL of ice-cooled trypsin TS for test of ulinastatin, mix, and put the tubes again in the water bath. One minute later add exactly 1 mL of *N*- α -benzoyl-L-arginine-4-nitroanilide TS, mix, and then put the tubes in the water bath. Exactly 2 minutes later add exactly 0.1 mL of diluted acetic acid (100) (1 in 2) to stop the enzyme reaction, and determine the absorbances of the solutions so obtained at 405 nm using water as the blank. Prepare a calibration curve using the absorbances obtained with the standard solutions, and calculate ulinastatin Units in the sample solution from its absorbance by using this curve.

Containers and storage Containers—Tight containers.
Storage—Preserve at -20°C or lower.

Urea

尿素



$\text{CH}_4\text{N}_2\text{O}$: 60.06
Urea [57-13-6]

Urea contains not less than 99.0% of $\text{CH}_4\text{N}_2\text{O}$.

Description Urea occurs as colorless to white crystals or crystalline powder. It is odorless, and has a cooling, saline taste.

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

A solution of Urea (1 in 100) is neutral.

Identification (1) Heat 0.5 g of Urea: it liquefies and the odor of ammonia is perceptible. Continue heating until the liquid becomes turbid, then cool. Dissolve the resulting

lump in a mixture of 10 mL of water and 2 mL of sodium hydroxide TS, and add 1 drop of copper (II) sulfate TS: a reddish purple color develops.

(2) Dissolve 0.1 g of Urea in 1 mL of water, and add 1 mL of nitric acid: a white, crystalline precipitate is formed.

Melting point $132.5 - 134.5^\circ\text{C}$

Purity (1) Chloride—Perform the test with 2.0 g of Urea. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.007%).

(2) Sulfate—Perform the test with 2.0 g of Urea. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.010%).

(3) Heavy metals—Proceed with 1.0 g of Urea 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) Ethanol-insoluble substances—Dissolve 5.0 g of Urea in 50 mL of warm ethanol (95), filter through a tared glass filter (G4), wash the residue with 20 mL of warm ethanol (95), and dry at 105°C for 1 hour: the mass of the residue is not more than 2.0 mg.

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

Assay Weigh accurately about 0.2 g of Urea, dissolve in water, and make exactly 200 mL. Measure exactly 5 mL of this solution into a Kjeldahl flask, and proceed as directed under the Nitrogen Determination.

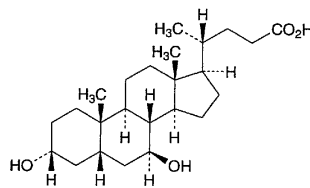
Each mL of 0.005 mol/L sulfuric acid VS
= 0.30028 mg of $\text{CH}_4\text{N}_2\text{O}$

Containers and storage Containers—Well-closed containers.

Ursodeoxycholic Acid

Ursodesoxycholic Acid

ウルソデオキシコール酸



$\text{C}_{24}\text{H}_{40}\text{O}_4$: 392.57
 $3\alpha,7\beta$ -Dihydroxy-5 β -cholan-24-oic acid [128-13-2]

Ursodeoxycholic Acid, when dried, contains not less than 98.5% of $\text{C}_{24}\text{H}_{40}\text{O}_4$.

Description Ursodesoxycholic Acid occurs as white crystals or powder. It is odorless, and has a bitter taste.

It is freely soluble in ethanol (95), in ethanol (99.5) and in acetic acid (100), slightly soluble in chloroform, very slightly soluble in diethyl ether, and practically insoluble in water.

It dissolves in sodium hydroxide TS.

Identification Dissolve 0.01 g of Ursodeoxycholic Acid in