cording to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of Nicomol according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(6) Related substances—Dissolve 0.20 g of Nicomol in 20 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add chloroform to make exactly 20 mL. Pipet 2 mL of this solution, add chloroform to make exactly 20 mL, and use this solution as the standard solution. 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of dichloromethane, ethanol (95), acetonitrile and ethyl acetate (5:3:1:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

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

Assay Weigh accurately about 1.5 g of Nicomol, previously dried, add exactly 40 mL of 0.5 mol/L sodium hydroxide VS, and boil gently under a reflux condenser connected to a carbon dioxide absorption tube (soda lime) for 10 minutes. After cooling, titrate immediately the excess sodium hydroxide with 0.25 mol/L sulfuric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.5 mol/L sodium hydroxide VS
= 80.08 mg of $C_{34}H_{32}N_4O_9$

Containers and storage Containers—Tight containers.

Nicomol Tablets

ニコモール錠

Nicomol Tablets contain not less than 95% and not more than 105% of the labeled amount of nicomol ($C_{34}H_{32}N_4O_9$: 640.64).

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

Identification To a portion of powdered Nicomol Tablets, equivalent to 0.5 g of Nicomol according to the labeled amount, add 20 mL of chloroform, shake, and filter. Evaporate the filtrate on a water bath to dryness. Proceed with the residue as directed in the Identification (1) and (2) under Nicomol.

Dissolution test Perform the test with 1 tablet of Nicomol Tablets at 75 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of the 1st fluid under the Disintegration Test. Take 20 mL or more of the dissolved solution 60 minutes after starting the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, pipet 2 mL of the subsequent, add the 1st fluid to make exactly 25 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of nicomol for assay, previously dried at 105°C for 4 hours, dissolve in the 1st fluid to make exactly 100 mL, then pipet 2 mL of this solution, add the 1st fluid to make exactly 100 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 262 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Nicomol Tablets in 60 minutes is not less than 75%.

Dissolution rate (%) with respect to the labeled amount of nicomol ($C_{34}H_{32}N_4O_9$)

$$= W_S \times \frac{A_T}{A_S} \times \frac{1}{C} \times 225$$

W_S: Amount (mg) of nicomol for assay.
C: Labeled amount (mg) of nicomol ($C_{34}H_{32}N_4O_9$) in 1 tablet.

Assay Weigh accurately not less than 20 Nicomol Tablets and powder. Weigh accurately a portion of the powder, equivalent to about 1 g of nicomol ($C_{34}H_{32}N_4O_9$), add 100 mL of 1 mol/L hydrochloric acid TS, shake well, add water to make exactly 500 mL, and filter. Discard the first 50 mL of the filtrate, pipet 2 mL of the subsequent filtrate, add 50 mL of 1 mol/L hydrochloric acid TS and water to make exactly 250 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.08 g of nicomol for assay, previously dried at 105°C for 4 hours, dissolve in 50 mL of 1 mol/L hydrochloric acid TS, and add water to make exactly 100 mL. Pipet 2 mL of this solution, add 20 mL of 1 mol/L hydrochloric acid TS and water to make exactly 100 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 262 nm as directed under the Ultraviolet-visible Spectrophotometry.

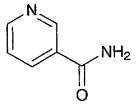
Amount (mg) of nicomol ($C_{34}H_{32}N_4O_9$)
= amount (mg) of nicomol for assay

$$\times \frac{A_T}{A_S} \times \frac{25}{2}$$

Containers and storage Containers—Tight containers.

Nicotinamide

ニコチン酸アミド



$C_6H_6N_2O$: 122.12
Pyridine-3-carboxamide [*98-92-0*]

Nicotinamide, when dried, contains not less than 98.5% of $C_6H_6N_2O$.

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