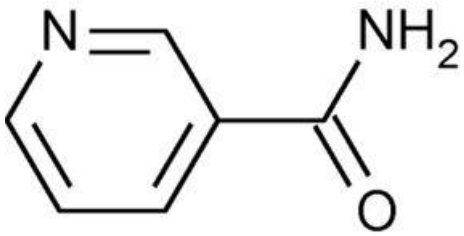
Niacinamide



$C_6H_6N_2O$ 122.12

3-Pyridinecarboxamide.

Nicotinamide [98-92-0].

Niacinamide contains not less than 98.5 percent and not more than 101.5 percent of C6H6N2O, calculated on the dried basis.

Packaging and storage— Preserve in tight containers.

Identification—

A: Infrared Absorption 197K .

B: Ultraviolet Absorption 197U —

Solution: 20 µg per mL.

Medium: water.

Ratio: A245/A262, between 0.63 and 0.67.

Melting range 741 : between 128 and 131 .

Loss on drying 731 — Dry it over silica gel for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition 281 : not more than 0.1%.

Heavy metals, Method II 231 : 0.003%.

Readily carbonizable substances 271 — Dissolve 200 mg in 5 mL of sulfuric acid TS: the solution has no more color than Matching Fluid A.

Assay—

Mobile phase— Prepare a filtered and degassed solution containing 0.005 M sodium 1-heptanesulfonate and methanol (70:30).

Standard preparation— Transfer about 50 mg of USP Niacinamide RS, accurately weighed, to a 100-mL volumetric flask, dissolve in about 3 mL of water, dilute with Mobile phase to volume, and mix. Dilute 4.0 mL of the resulting solution with Mobile phase to 50.0 mL, and mix.

Resolution solution— Prepare a solution containing equal volumes of the Standard preparation and of a niacin solution similarly prepared and having the same concentration.

Assay preparation— Prepare as directed under Standard preparation, using Niacinamide instead of the Reference Standard.

Chromatographic system—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column containing packing L1. The flow rate is about 2 mL per minute. Chromatograph the Resolution solution: the resolution, R, between the niacin and niacinamide peaks is not less than 3.0. Chromatograph replicate injections of the Standard preparation, and record the peak responses as directed for Procedure: the relative standard deviation is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_6H_6N_2O$ in the portion of Niacinamide taken by the formula:

$$1250C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Niacinamide RS in the Standard preparation, and r_U and r_S are the peak responses for the Assay preparation and the Standard preparation, respectively.