

Niacin Tablets

Niacin Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_5NO_2$.

Packaging and storage— Preserve in well-closed containers.

Identification—

A: Heat a quantity of finely powdered Tablets, equivalent to about 500 mg of niacin, with 25 mL of alcohol on a steam bath for a few minutes, filter, and wash the residue with a few mL of hot alcohol. To the filtrate add 30 mL of water, and evaporate to about 25 mL on the steam bath. Cool, filter if insoluble matter separates, and evaporate the filtrate to about 10 mL. Cool, and place in a refrigerator for 1 hour. Filter the separated niacin with suction, wash it with a few mL of cold alcohol, and dry at 105 °C or 1 hour: the niacin so obtained responds to [Identification](#) tests A and B under [Niacin](#).

B: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation obtained as directed in the [Assay](#).

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 60 minutes.

Procedure— Determine the amount of $C_6H_5NO_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 260 nm of filtered portions of the solution under test, suitably diluted with Medium, if necessary, in comparison with a Standard solution having a known concentration of about 0.02 mg of [USP Niacin RS](#) per mL in the same medium.

Tolerances— Not less than 65% (Q) of the labeled amount of $C_6H_5NO_2$ is dissolved in 60 minutes.

[Uniformity of dosage units](#) [905](#) : meet the requirements.

Assay—

Mobile phase— Prepare a 0.005 M solution of sodium 1-hexanesulfonate in water. Mix 78 parts of this solution with 14 parts of methanol, 7 parts of acetonitrile, and 1 part of glacial acetic acid, stir, filter, and degas. Make adjustments if necessary.

Standard preparation— Transfer an accurately weighed quantity of [USP Niacin RS](#) to a suitable volumetric flask, add water, heat on a steam bath, sonicate, shake by mechanical means, cool, and dilute with water to volume to obtain a solution having a known concentration of about 0.5 mg per mL. Transfer 1.0 mL of this solution to a 10-mL volumetric flask, dilute with water to volume, and mix.

Assay preparation— Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed quantity of the powder equivalent to about 500 mg of Niacin to a 100-mL volumetric flask, add 50 mL of water, and heat on a steam bath for 30 minutes. Sonicate for 2 minutes, shake by mechanical means for 15 minutes, and cool to room temperature. Dilute with water to volume, mix, and filter. Transfer 1.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system—The liquid chromatograph is equipped with a 262-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 1.3 mL per minute.

Chromatograph replicate injections of the Standard preparation, and record the peak responses as directed for Procedure: the column efficiency determined from the analyte peak is not less than 1000 theoretical plates, the tailing factor for the analyte peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— [Note—Use peak areas where peak responses are indicated.] 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 C₆H₅NO₂ in the portion of Tablets taken by the formula:

$$10,000C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Niacin RS](#) in the Standard preparation, and r_U and r_S are the peak responses for niacin obtained from the Assay preparation and the Standard preparation, respectively.