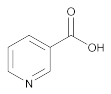
C_S = concentration of USP Nevirapine Anhydrous RS in the *Standard solution* (mg/mL)
C_U = nominal concentration nevirapine in the *Sample solution* (mg/mL)

[NOTE—Disregard all peaks due to the solvent or excipients and impurity peaks less than 0.1%.]

Acceptance criteria
Individual unknown impurity: NMT 0.1%
Total unknown impurities: NMT 0.2%

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Nevirapine Anhydrous RS
  USP Nevirapine Related Compound A RS
  5,11-Dihydro-6*H*-11-ethyl-4-methyl-dipyrido[3,2-*b*:2′,3′- *e*][1,4]diazepin-6-one.
  $C_{14}H_{14}N_4O$ 254.29

Niacin



$C_6H_5NO_2$ 123.11
3-Pyridinecarboxylic acid;
Nicotinic acid [59-67-6].

DEFINITION
Niacin contains NLT 99.0% and NMT 101.0% of niacin ($C_6H_5NO_2$), calculated on the dried basis.

IDENTIFICATION
- **A. INFRARED ABSORPTION** ⟨**197M**⟩
- **B. ULTRAVIOLET ABSORPTION** ⟨**197U**⟩
  Wavelength range: 200–300 nm
  Sample solution: 20 µg/mL in *Buffer solution*, prepared as directed in the *Assay*
  Acceptance criteria: Meets the requirements in the chapter. The A_{237}/A_{262} ratio is 0.46–0.50.

ASSAY
- **PROCEDURE**
  Buffer solution: Dissolve 6.8 g of monobasic potassium phosphate in 1000 mL of water. Adjust with 50% sodium hydroxide solution to a pH of 7.0.
  Standard solution: 0.02 mg/mL of USP Niacin RS in *Buffer solution*
  Sample solution: 0.02 mg/mL of Niacin in *Buffer solution*
  Blank: *Buffer solution*
  Instrumental conditions
  (See *Spectrophotometry and Light-Scattering* ⟨851⟩.)
  Mode: UV-Vis
  Analytical wavelength: 262 nm
  Cell: 1 cm
  Analysis
  Samples: *Standard solution, Sample solution*, and *Blank*
  Determine the absorbances of the solutions against the *Blank*.
  Calculate the percentage of niacin ($C_6H_5NO_2$) in the portion of Niacin taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of USP Niacin RS in the *Standard solution* (µg/mL)
C_U = concentration of Niacin in the *Sample solution* (µg/mL)

Acceptance criteria: 99.0%–101.0% on the dried basis

IMPURITIES
- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.1%
- **CHLORIDE AND SULFATE,** *Chloride* ⟨**221**⟩
  Standard: 0.15 mL of 0.020 N hydrochloric acid
  Sample: 0.50 g of Niacin
  Acceptance criteria: NMT 0.02%
- **CHLORIDE AND SULFATE,** *Sulfate* ⟨**221**⟩
  Standard: 0.10 mL of 0.020 N sulfuric acid
  Sample: 0.50 g of Niacin
  Acceptance criteria: NMT 0.02%
- **HEAVY METALS,** *Method I* ⟨**231**⟩
  Test preparation: Mix 1 g with 4 mL of 1 N acetic acid, and dilute with water to 25 mL. Heat gently until solution is complete, and cool.
  Acceptance criteria: NMT 20 ppm
- **ORDINARY IMPURITIES** ⟨**466**⟩
  Standard solutions and **Test solution:** Use water as the solvent.
  Eluant: A mixture of methanol and 0.1 N hydrochloric acid (9:1)
  Visualization: 1
  Analysis: Proceed as directed in the chapter.
  Acceptance criteria: NMT 2.0% of total ordinary impurities

SPECIFIC TESTS
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 105° for 1 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Niacin RS

Niacin Injection

» Niacin Injection is a sterile solution of Niacin and niacin sodium in Water for Injection, made with the aid of Sodium Carbonate or Sodium Hydroxide. It contains not less than 95.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_5NO_2$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Niacin RS

Identification—To a volume of Injection, equivalent to about 100 mg of niacin, add 0.3 mL of 3 N hydrochloric acid, evaporate, if necessary, on a steam bath to about 2 mL, and allow to stand for 1 hour in a cool place. Filter by suction, wash with small volumes of ice-cold water until the last washing does not give a reaction for chloride, and dry at 105° for 1 hour: the niacin so obtained responds to *Identification* tests *A* and *B* under *Niacin*.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 3.5 USP Endotoxin Units per mg of niacin.

pH ⟨791⟩: between 4.0 and 6.0.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—Proceed with Injection as directed for *Chemical Method* under *Niacin or Niacinamide Assay* ⟨441⟩, using *Standard Niacin Preparation* as the *Standard Preparation* in the *Assay Procedure*, and the following as the *Assay Preparation.* Transfer an accurately measured volume of Injection, equivalent to about 50 mg