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Nevirapine Tablets

DEFINITION
Nevirapine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of nevirapine ($C_{15}H_{14}N_4O$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Transfer a portion of powdered Tablets equivalent to 25 mg of nevirapine to a 50-mL volumetric flask. Dissolve in 10 mL of methylene chloride. Swirl the solution for 30–60 s, and pass through a medium sintered-glass, fritted vacuum funnel. Using a glass syringe, pass the filtrate through a Teflon filter of 0.45-µm pore size. Dry the extract at 105° for a minimum of 1 h.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (23:77)

Diluent: Dehydrated alcohol and water (1:1)

System suitability solution: 0.025 mg/mL of USP Nevirapine Anhydrous RS and 0.025 mg/mL of USP Nevirapine Related Compound A RS in *Diluent*

Standard solution: 0.025 mg/mL of USP Nevirapine Anhydrous RS in *Diluent*

Sample stock solution: Nominally 1 mg/mL of nevirapine in *Diluent* prepared as follows. Transfer nevirapine, from finely powdered Tablets (NLT 20), to a suitable size volumetric flask, and add 75% of the final volume with *Diluent*. Sonicate the solution for 20 min, then shake for 20 min. Cool to room temperature, and dilute with *Diluent* to volume. Centrifuge a portion of the resulting solution at 1500 rpm for 5 min.

Sample solution: Nominally 0.025 mg/mL of nevirapine in *Diluent* from the *Sample stock solution*. Filter a portion of the resulting solution, and discard the first 2 mL of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 214 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 1 mL/min

Injection size: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between nevirapine and nevirapine related compound A, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nevirapine ($C_{15}H_{14}N_4O$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of nevirapine from the *Sample solution*

r_S = peak response of nevirapine from the *Standard solution*

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)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.1 M phosphate buffer, pH 2.0 (transferring 3.9 mL/L of concentrated phosphoric acid and 5.73 g/L of monobasic sodium phosphate monohydrate in water, adjust with phosphoric acid to a pH of 2.0 ± 0.02); 900 mL

Apparatus 2: 50 rpm. [Note—Use stainless steel paddles only. Do not use paddles coated with polytetrafluoroethylene.]

Time: 60 min

Mobile phase, Diluent, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard stock solution A: 0.054 mg/mL of USP Nevirapine Anhydrous RS. Add 10% of the final volume with alcohol and 50% of the final volume of *Medium*. Sonicate for 20 min to dissolve, allow to cool to room temperature, and dilute with *Medium* to volume.

Standard stock solution B: 0.028 mg/mL of USP Nevirapine Related Compound A RS. Add 0.8% of the final volume of *Diluent*, sonicate until completely dissolved, and dilute with *Medium* to volume.

Standard solution: 0.014 mg/mL of USP Nevirapine Anhydrous RS from *Standard stock solution A* in *Medium*

System suitability solution: 0.014 mg/mL of USP Nevirapine Anhydrous RS from *Standard stock solution A* and 0.014 mg/mL of USP Nevirapine Related Compound A RS from *Standard stock solution B* in *Medium*

Sample solution: Pass 20 mL of the solution under test through a suitable nylon or glass fiber filter of 0.45-µm pore size, and dilute with *Medium* to obtain a solution having a final concentration of 0.014 mg/mL of nevirapine.

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of nevirapine ($C_{15}H_{14}N_4O$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/D_U) \times V \times (100/L)$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

D_U = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of nevirapine ($C_{15}H_{14}N_4O$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase, Diluent, System suitability solution, Sample stock solution, and **Sample solution:** Proceed as directed in the *Assay*.

Standard solution: 0.125 µg/mL of USP Nevirapine Anhydrous RS in *Diluent*

Chromatographic system: Proceed as directed in the *Assay*, except use a run time of at least 13 min.

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between nevirapine and nevirapine related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each unknown impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each unknown impurity from the *Sample solution*

r_S = peak response of nevirapine from the *Standard solution*

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NEVIRAPINE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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