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# Nevirapine Extended-Release Tablets

**DEFINITION**

Nevirapine Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of nevirapine (C<sub>15</sub>H<sub>14</sub>N<sub>4</sub>O).

**IDENTIFICATION**

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the nevirapine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

**ASSAY**

• **PROCEDURE**

**Solution A:** [Acetonitrile](#) and water (15:85)

**Solution B:** [Acetonitrile](#) and water (40:60)

**Mobile phase:** See [Table 1](#).

Table 1

| Time<br>(min) | Solution A<br>(%) | Solution B<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 100               | 0                 |
| 7             | 100               | 0                 |
| 23            | 0                 | 100               |
| 33            | 0                 | 100               |
| 33.1          | 100               | 0                 |
| 48            | 100               | 0                 |

[NOTE—These gradient elution times are established on an HPLC system with a hold time of approximately 7 min based on the dwell volume of 0.7 mL. Adjust the start of the gradient to be approximately 2 min after the retention time of nevirapine and adjust the remaining gradient accordingly. The hold time (X) can be calculated using the formula: X = (11.2 mL – dwell volume)/flow rate.]

**Diluent:** [Acetonitrile](#) and [water](#) (30:70)

**Standard solution:** 0.5 mg/mL of [USP Nevirapine Anhydrous RS](#) in *Solution B*. Sonicate if necessary to dissolve, before final dilution.

**Sample stock solution:** Nominally 2 mg/mL of nevirapine prepared as follows. Transfer an appropriate number of Tablets to a suitable volumetric flask. Add 50% of the flask volume of [acetonitrile](#) and shake for 30 min. Add 30% of the flask volume of [water](#) and continue shaking for another 30 min. Allow it to stand for at least 1 h and dilute with water to volume. Centrifuge a portion and use the supernatant.

**Sample solution:** Nominally 0.5 mg/mL of nevirapine in *Diluent* from the *Sample stock solution*

**Chromatographic system**

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** UV 282 nm. For *Identification A*, use a diode array detector in the range of 210–400 nm.

**Column:** 3.9-mm × 15-cm; 5-µm packing [L1](#)

**Column temperature:** 35°

**Flow rate:** 1.5 mL/min

**Injection volume:** 25 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

**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 of nevirapine in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**

- [DISSOLUTION \(711\)](#)

**▲Test 1▲** (RB 1-May-2018)

**Medium:** 0.04 M sodium phosphate buffer pH 6.8 containing 2% [sodium dodecyl sulfate](#) prepared as follows. Dissolve 6.0 g of [monobasic sodium phosphate](#) in 800 mL of [water](#) and adjust with a 50% [sodium hydroxide](#) solution to a pH of 6.8. Add 20 g of [sodium dodecyl sulfate](#) and dilute with [water](#) to 1000 mL; 900 mL.

**Apparatus 1:** 75 rpm**Times****For Tablets labeled to contain 100 mg:** 1, 5, and 12 h**For Tablets labeled to contain 400 mg:** 2, 8, and 20 h**Mobile phase:** [Acetonitrile](#) and water (18:82)**Standard solution:** ( $L/900$ ) mg/mL of [USP Nevirapine Anhydrous RS](#) in *Medium*, where  $L$  is the label claim in mg/Tablet prepared as follows.Transfer a weighed quantity of [USP Nevirapine Anhydrous RS](#) to a suitable volumetric flask and add [ethyl alcohol](#) to fill 12% of the flask volume. Sonicate for 15 min or until dissolved. Allow to cool to room temperature and dilute with *Medium* to volume.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- $\mu$ m pore size.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 282 nm**Column:** 3.9-mm  $\times$  15-cm; 5- $\mu$ m packing [L1](#)**Column temperature:** 40°**Flow rate:** 1.5 mL/min**Injection volume:** 20  $\mu$ L**Run time:** About 1.6 times the retention time of nevirapine**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the concentration ( $C_i$ ) of nevirapine ( $C_{15}H_{14}N_4O$ ) dissolved in the portion of the sample withdrawn at each time point ( $i$ ) (mg/mL):

$$C_i = (r_U/r_S) \times C_S$$

 $r_U$  = 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)Calculate the percentage of the labeled amount of nevirapine ( $C_{15}H_{14}N_4O$ ) dissolved at each time point ( $i$ ):

$$\text{Result}_1 = C_i \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$