

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2022
Document Type: USP Monographs
DocId: GUID-9D3B078E-584B-4B19-9ABD-1A64CB0DC9E6_2_en-US
DOI: https://doi.org/10.31003/USPNF_M3455_02_01
DOI Ref: yu5h7

© 2025 USPC
Do not distribute

Add the following:

^Etravirine Tablets

DEFINITION
Etravirine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of etravirine ($C_{20}H_{15}BrN_6O$).

- IDENTIFICATION**
- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K or 197A
 - **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**
Protect solutions containing etravirine from light.
Buffer: 10 mM [ammonium formate](#) in [water](#)
Diluent: [Acetonitrile](#) and *Buffer* (50:50, v/v)
Solution A: 50 mM [formic acid](#) in *Buffer*
Solution B: [Acetonitrile](#)
Solution C: [Methanol](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	60	30	10
35	0	0	100
37	60	30	10
45	60	30	10

Standard solution: 0.10 mg/mL of [USP Etravirine RS](#) prepared as follows. Transfer a suitable amount of [USP Etravirine RS](#) to a suitable volumetric flask and dissolve in 5% of the total volume of [1-methyl-2-pyrrolidone](#). Dilute with *Diluent* to volume.

Sample solution: Nominally 0.10 mg/mL of etravirine in *Diluent* prepared as follows. Transfer a portion equivalent to NLT 50 mg of etravirine from finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add 5% of the flask volume of *Diluent* and shake for 5 min. Add 5% of the flask volume of [1-methyl-2-pyrrolidone](#) and shake for 30 min. Dilute with *Diluent* to volume. Allow the solution to stand for 4 h at room temperature. Pass a portion of the solution through a suitable filter of 0.45-µm pore size, and use the clear filtrate.

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

Mode: LC
Detector: UV 310 nm
Column: 3.0-mm × 15-cm; 5-µm packing [L1](#)
Column temperature: 35°
Flow rate: 0.6 mL/min
Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of etravirine ($C_{20}H_{15}BrN_6O$) in the portion of Tablets taken:

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

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

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

C_S = concentration of [USP Etravirine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of etravirine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Protect solutions containing etravirine from light.

Solution A: 0.01 M [hydrochloric acid](#)

Solution B: 2.25% [sodium lauryl sulfate](#) in *Solution A*

Medium

For Tablets labeled to contain 25 and 100 mg: 500 mL of *Solution A* and 400 mL of *Solution B*

For Tablets labeled to contain 200 mg: 1000 mL of *Solution A* and 800 mL of *Solution B*

Apparatus 2

For Tablets labeled to contain 25 and 100 mg: 50 rpm

For Tablets labeled to contain 200 mg: 70 rpm

Time

For Tablets labeled to contain 25 and 100 mg: 45 min

For Tablets labeled to contain 200 mg: 30 min

Mobile phase: [Acetonitrile](#) and 0.5% phosphoric acid (65:35)

Standard solution: 0.111 mg/mL of [USP Etravirine RS](#) in *Medium* for Tablets labeled to contain 100 and 200 mg; 0.0278 mg/mL of [USP Etravirine RS](#) in *Medium* for Tablets labeled to contain 25 mg, prepared as follows. Transfer a suitable amount of [USP Etravirine RS](#) to a suitable volumetric flask and dissolve in 5% of the total volume of [1-methyl-2-pyrrolidone](#). Add [acetonitrile](#) to 50% of the total volume, equilibrate to room temperature, and dilute with *Solution B* to volume.

Sample solution: Place 1 Tablet in each vessel filled with a volume of *Solution A* as specified in *Medium*. After 10 min, add a volume of preheated *Solution B* as specified in *Medium* and reset the time to zero. Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 3.0-mm × 5.0-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 0.5 mL/min

Injection volume

For Tablets labeled to contain 25 mg: 40 μL

For Tablets labeled to contain 100 and 200 mg: 10 μL

Run time: NLT 2 times the retention time of etravirine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0