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Efavirenz Tablets

DEFINITION

Efavirenz Tablets contain NLT 92.0% and NMT 108.0% of the labeled amount of efavirenz (C₁₄H₉ClF₃NO₂).

IDENTIFICATION

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197K

Sample solution: Completely remove the coating film from a Tablet using a mortar and pestle to crack the Tablet, grind the contents into fine powder, and place the powder into a suitable container. Dissolve the contents in about 5 mL of acetonitrile by mixing on a vortex mixer. Allow to settle, remove about 3 mL of the solution, and centrifuge for about 5 min using a suitable container. Transfer 1–2 mL of supernatant to a clean suitable container, and evaporate to dryness under nitrogen. Mix 0.5–1 mg of the powder with 200 mg of potassium bromide.

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

Diluent: Acetonitrile and water (500:500)

Solution A: Methanol, trifluoroacetic acid, and water (100:0.5:900)

Solution B: Methanol, trifluoroacetic acid, and water (900:0.5:100)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
16	50	50
23	35	65
28	30	70
29	20	80
31	20	80
32	60	40
40	60	40

Standard stock solution 1: 0.2 mg/mL of [USP Efavirenz Related Compound B RS](#) in *Diluent*

Standard stock solution 2: 5 mg/mL of [USP Efavirenz RS](#) in *Diluent*. Sonicate to dissolve before diluting to final volume.

Standard solution: 250 µg/mL of [USP Efavirenz RS](#) and 1 µg/mL of [USP Efavirenz Related Compound B RS](#) in *Diluent* prepared from *Standard solution stock 2* and *Standard stock solution 1*, respectively. Store protected from light. For the HPLC analysis, it is recommended to use polypropylene vials, because degradation may occur with glass containers.

Sample stock solution: Nominally, 12 mg/mL of efavirenz in *Diluent* prepared as follows. Transfer NLT 10 Tablets to a suitable container, and extract the contents in *Diluent* by mixing for about 90 min. Store protected from light.

Sample solution: Nominally, 240 µg/mL of efavirenz in *Diluent* prepared as follows. Filter a portion of the *Sample stock solution*, and dilute the filtrate with *Diluent*. Store protected from light. For the HPLC analysis, it is recommended to use polypropylene vials, because degradation may occur with glass containers.

Chromatographic system

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

Mode: LC**Detector:** UV 250 nm**Column:** 4.6-mm × 15-cm; 5-μm packing L10**Column temperature:** 40°**Flow rate:** 1.5 mL/min**Injection volume:** 35 μL**System suitability****Sample:** *Standard solution*

[NOTE—The typical retention times for efavirenz related compound B and efavirenz are 0.9 and 1.0, respectively.]

Suitability requirements**Resolution:** NLT 1.2 between efavirenz related compound B and efavirenz**Relative standard deviation:** NMT 2.0% for efavirenz**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of efavirenz ($C_{14}H_9ClF_3NO_2$) in the portion of Tablets taken:

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

 r_U = peak response of efavirenz from the *Sample solution* r_S = peak response of efavirenz from the *Standard solution* C_S = concentration of [USP Efavirenz RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of efavirenz in the *Sample solution* (mg/mL)**Acceptance criteria:** 92.0%–108.0%**PERFORMANCE TESTS**• [DISSOLUTION \(711\)](#)**Medium:** 2.0% (w/v) sodium lauryl sulfate in water; 1000 mL. Do not deaerate.**Apparatus 2:** 50 rpm, with helix sinker. In addition, paddle and shaft must be composed of stainless steel and not coated with Teflon or other material. Also, all sampling devices and dissolution vessels must be washed with methanol or ethanol followed by a water wash.**Time:** 30 min**Standard solution:** ($L/1000$) mg/mL of [USP Efavirenz RS](#) in *Medium*, where L is the Tablet label claim in mg. A small volume of methanol, NMT 1% of the final volume, could be used to solubilize efavirenz. Dilute this solution with *Medium* to obtain a final concentration of about 0.012 mg/mL.**Sample solution:** Pass a portion of the solution under test through a suitable polyethylene filter, and dilute with *Medium* to obtain a concentration similar to the *Standard solution*, assuming complete dissolution of the Tablet label claim.**Instrumental conditions****Analytical wavelength:** UV 247 nm**Cell:** 1 cm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of efavirenz ($C_{14}H_9ClF_3NO_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) V = volume of *Medium*, 1000 mL D = dilution for the *Sample solution* L = label claim (mg/Tablet)**Tolerances:** NLT 80% (Q) of the labeled amount of efavirenz ($C_{14}H_9ClF_3NO_2$) is dissolved.**Change to read:**• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): ▲Meet the requirements▲ (CN 1-Aug-2023)**Procedure for content uniformity**