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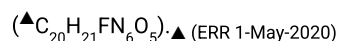
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Raltegravir Tablets

DEFINITION

Change to read:

Raltegravir Tablets contain an amount of Raltegravir Potassium equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of raltegravir



IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197A or 197K](#) (CN 1-May-2020)

Sample: Grind a Tablet, and use a suitable amount of the powdered Tablet to prepare a specimen.

Acceptance criteria: The spectrum obtained from the *Sample* shows bands at approximately 1633, 1515, 1188, 810, and 728 cm^{-1} , similar to the spectrum from the Standard similarly obtained. [NOTE—Peak positions may vary slightly between instruments (within $\pm 10 \text{ cm}^{-1}$). Other peaks may be present in the spectra that do not appear in this list.]

- **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

Change to read:

• PROCEDURE

Buffer: 1.36 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (29:71)

Solution A: [Acetonitrile](#) and [water](#) (50:50)

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

Standard solution: 0.22 mg/mL of [USP Raltegravir Potassium RS](#) in *Diluent*

Sample stock solution: Nominally equivalent to 8 mg/mL of raltegravir from Tablets prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask and dilute with *Solution A* to volume. Stir the flask vigorously for 1 h. Centrifuge a portion of the solution and use the supernatant for *Sample solution* preparation.

Sample solution: Nominally 0.2 mg/mL of raltegravir in *Diluent* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 15-cm; 5- μm packing [L1](#)

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 30 μL

Run time: NLT 1.5 times the retention time of raltegravir

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of raltegravir ($\text{C}_{20}\text{H}_{21}\text{FN}_6\text{O}_5$) in the portion of Tablets labeled:



$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

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

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

M_{r1} = molecular weight of raltegravir, ▲444.42▲ (ERR 1-May-2020)

M_{r2} = molecular weight of raltegravir potassium, 482.51

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: [Water](#), 900 mL, deaerated

Apparatus 2: 100 rpm with sinker

Times: 15 and 60 min

Buffer: 1.36 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (38:62)

Diluent: [Acetonitrile](#) and [water](#) (20:80)

Standard solution: 0.48 mg/mL of [USP Raltegravir Potassium RS](#) in *Diluent*. Sonicate, if necessary, to dissolve prior to final dilution.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 303 nm

Column: 4.6-mm × 10-cm; packing L1

Column temperature: 40°

Flow rate: 5 mL/min

Injection volume: 10 µL

Run time: 1 min

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of raltegravir ($C_{20}H_{20}FN_6O_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times (1/L) \times V \times D \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*, if needed

M_{r1} = molecular weight of raltegravir, ▲444.42▲ (ERR 1-May-2020)