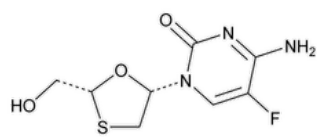


Add the following:

^Emtricitabine



$C_8H_{10}FN_3O_3S$ 247.24
(2*R*-*cis*)-4-Amino-5-fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-2(1*H*)-pyrimidinone;
5-Fluoro-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine CAS RN[®]: 143491-57-0; UNII: G70B4ETF4S.

DEFINITION
Emtricitabine contains NLT 98.0% and NMT 102.0% of emtricitabine ($C_8H_{10}FN_3O_3S$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K
- **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**
Solution A: 2.72 g/L of [potassium phosphate monobasic](#) in [water](#)
Solution B: [Methanol](#) and *Solution A* (80:20)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35	89	11
47	0	100
59	0	100
60	100	0
65	100	0

Standard solution: 1 mg/mL of [USP Emtricitabine RS](#) in [water](#). Sonicate, if necessary, to dissolve prior to final dilution.
Sample solution: 1 mg/mL of Emtricitabine in [water](#). Sonicate, if necessary, to dissolve prior to final dilution.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 280 nm
Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)
Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of emtricitabine ($C_8H_{10}FN_3O_3S$) in the portion of Emtricitabine taken:

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

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

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

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 1 mg/mL of [USP Emtricitabine System Suitability Mixture B RS](#) in [water](#). Sonicate, if necessary, to dissolve prior to final dilution.

Standard solution: 1 µg/mL of [USP Emtricitabine RS](#) in [water](#) prepared from the *Standard solution* in the Assay

Sensitivity solution: 0.5 µg/mL of [USP Emtricitabine RS](#) in [water](#) prepared from the *Standard solution*

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between emtricitabine and emtricitabine 5-fluorouracil analog, *System suitability solution*

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

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any impurity in the portion of Emtricitabine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of any impurity from the *Sample solution*

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

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

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

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#). Disregard the peak due to the emtricitabine diastereomer with a relative retention time of 1.04, if present, as it is monitored in a separate method.

Table 2