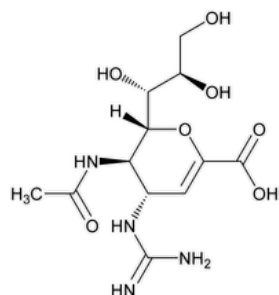


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Zanamivir



$C_{12}H_{20}N_4O_7$ 332.31

D-glycero-D-galacto-Non-2-enonic acid, 5-(acetamino)-4-[(aminoiminomethyl)amino]-2,6-anhydro-3,4,5-trideoxy-;
 5-Acetamido-2,6-anhydro-3,4,5-trideoxy-4-guanidino-D-glycero-D-galacto-non-2-enonic acid CAS RN[®]: 139110-80-8; UNII: L6O3XI777I.

DEFINITION

Zanamivir contains NLT 98.0% and NMT 102.0% of zanamivir ($C_{12}H_{20}N_4O_7$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

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

Wavenumber range: 4000 cm^{-1} to 400 cm^{-1}

- **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

Mobile phase: Acetonitrile and 7.5 mM sulfuric acid (60:40). Adjust with ammonia TS to a pH of 6.2.

Resolution solution: Prepare 2.5 $\mu g/mL$ of *talo*-zanamivir and 0.05 mg/mL of zanamivir from [USP Zanamivir Resolution Mixture RS](#) in *Mobile phase*.

Standard solution: 0.045 mg/mL of [USP Zanamivir RS](#) in *Mobile phase*

Sample solution: 0.045 mg/mL of Zanamivir in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 234 nm

Column: 4.6-mm $\times$ 25-cm; 5- μm packing L82

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

Samples: *Resolution solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between *talo*-zanamivir and zanamivir, *Resolution solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of zanamivir ($C_{12}H_{20}N_4O_7$) in the portion of Zanamivir taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase: Proceed as directed in the Assay.

System suitability solution: Prepare 0.45 mg/mL of zanamivir and 9 µg/mL each of imidazole, imidazole carboximidamide, zanamivir urea analog, 4-amino zanamivir, 4-biguanide zanamivir, and *talo*-zanamivir from [USP Zanamivir Related Compounds Mixture RS](#) in *Mobile phase*.

Sample solution: 0.45 mg/mL of Zanamivir prepared as follows. Dissolve the sample using 40% of the final volume with water, and dilute with acetonitrile to volume.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm and 234 nm

Column: 4.6-mm × 25-cm; 5-µm packing L82

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between the peaks of *talo*-zanamivir and zanamivir at 234 nm

Analysis

Sample: *Sample solution*

Calculate the percentage of imidazole in the portion of Zanamivir taken:

$$\text{Result} = [(r_i/F)/(r_i/F + r_z)] \times 100$$

r_i = peak response of imidazole at 210 nm

F = relative response factor for imidazole (see [Table 1](#))

r_z = peak response of zanamivir at 210 nm

Calculate the percentage of imidazole carboximidamide and 4-biguanide zanamivir in the portion of Zanamivir taken:

$$\text{Result} = [(r_i/F)/(r_i/F + r_z)] \times 100$$

r_i = peak response of imidazole carboximidamide or 4-biguanide zanamivir at 234 nm

F = relative response factor for imidazole carboximidamide or 4-biguanide zanamivir (see [Table 1](#))

r_z = sum of the responses of all the peaks including the zanamivir peak at 234 nm

Calculate the percentage of *O*-triazinyl zanamivir, zanamivir urea analog, 4-amino zanamivir, *talo*-zanamivir, zanamivir dimer, and any other unspecified impurity in the portion of Zanamivir taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of *O*-triazinyl zanamivir, zanamivir urea analog, 4-amino zanamivir, *talo*-zanamivir, zanamivir dimer, or any other unspecified impurity at 234 nm

r_T = sum of the responses of all the peaks including the zanamivir peak at 234 nm