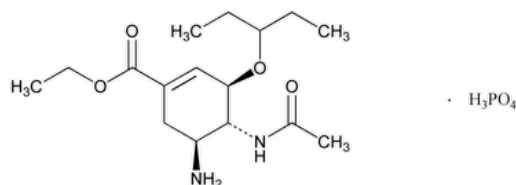


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Oseltamivir Phosphate



$C_{16}H_{28}N_2O_4 \cdot H_3PO_4$ 410.40

[3*R*-(3 α ,4 β ,5 α)]-Ethyl 4-(acetamino)-5-amino-3-(1-ethylpropoxy)-1-cyclohexene-1-carboxylate phosphate (1:1);

Ethyl (3*R*,4*R*,5*S*)-4-acetamido-5-amino-3-(1-ethylpropoxy)-1-cyclohexene-1-carboxylate, phosphate (1:1) CAS RN[®]: 204255-11-8; UNII: 4A3O49NGEZ.

DEFINITION

Oseltamivir Phosphate contains NLT 98.0% and NMT 101.5% of $C_{16}H_{28}N_2O_4 \cdot H_3PO_4$, calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197M**
- **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: Dissolve 6.8 g of potassium dihydrogen phosphate in 980 mL of water. Adjust with 1 M potassium hydroxide solution to a pH of 6.0, and dilute with water to 1 L.

Mobile phase: Methanol, acetonitrile, and *Solution A* (245:135:620)

Diluent: Methanol, acetonitrile, and water (245:135:620)

Standard solution: 1 mg/mL of [USP Oseltamivir Phosphate RS](#) in *Diluent*

Sample solution: 1 mg/mL of Oseltamivir Phosphate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

Column: 4.6-mm × 25-cm; packing L7

Column temperature: 50°

Flow rate: 1.2 mL/min

Injection size: 15 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{16}H_{28}N_2O_4 \cdot H_3PO_4$ in the portion of Oseltamivir Phosphate 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 Oseltamivir Phosphate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Oseltamivir Phosphate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.5% on the anhydrous basis

IMPURITIES

Change to read:

ORGANIC IMPURITIES

• PROCEDURE 1

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

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Oseltamivir Phosphate taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak response of each individual impurity from the *Sample solution*

r_s = peak response of oseltamivir phosphate from the *Standard solution*

C_s = concentration of [USP Oseltamivir Phosphate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Oseltamivir Phosphate in the *Sample solution* (mg/mL)

F = relative response factor from [Impurity Table 1](#)

Acceptance criteria

Individual impurities: See [Impurity Table 1](#).

Total impurities: NMT 0.7%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Oseltamivir acid ^a	0.17	1.4	0.3
Oseltamivir phenol ^b	0.51	2.7	0.1
Oseltamivir phosphate	1.00	1.0	—
Unspecified impurity	—	1.0	0.1
Total unspecified impurity	—	—	0.4

^a (3R,4R,5S)-4-Acetylamino-5-amino-3-(1-ethylpropoxy)-1-cyclohexene-1-carboxylic acid.

^b 4-Acetylamino-3-hydroxybenzoic acid ethyl ester.

• PROCEDURE 2: OSELTAMIVIR RELATED COMPOUND A

Buffer: 1.54 g/L of ammonium acetate in water

Mobile phase: Acetonitrile, water, and *Buffer* (3:6:1)

Stock solution A: 50 µg/mL of [USP Oseltamivir Related Compound A RS](#), prepared as follows: Dissolve in alcohol, using 5% of final volume, and dilute with water to volume.

Solution A: 1 µg/mL of [USP Oseltamivir Related Compound A RS](#) in water from *Stock solution A*