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Oseltamivir Phosphate Capsules

DEFINITION

Oseltamivir Phosphate Capsules contain Oseltamivir Phosphate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of oseltamivir ($C_{16}H_{28}N_2O_4$).

IDENTIFICATION

The retention time of the major peaks of the *Sample solution* corresponds to those of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• OSELTAMIVIR

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 0.01 N [phosphoric acid](#) (245:135:620)

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

Sample solution: Weigh the contents of 20 Capsules, and mix. Prepare the equivalent of about 1 mg of oseltamivir phosphate per mL, based on the label claim, by first dispersing a suitable portion of the powder in about 40% of the flask volume of *Diluent* using an ultrasonic bath for about 20 min, and diluting with *Diluent* to volume. Centrifuge an aliquot of this solution, and use the supernatant.

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 µL

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 the labeled amount of oseltamivir ($C_{16}H_{28}N_2O_4$) in the portion of Capsules taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of oseltamivir, 312.41▲ (CN 1-Aug-2024)

M_{r2} = molecular weight of oseltamivir phosphate, 410.40

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Detector: UV 240 nm

Standard solution: Prepare a solution in *Medium* having a known concentration of about 0.11 mg/mL of [USP Oseltamivir Phosphate RS](#).

Quantitatively dilute a portion of this solution with *Medium* to obtain a solution having a known concentration similar to the expected concentration in the solution under test.

Sample solution: Pass a portion of the solution under test through a suitable filter of 1-µm pore size.

Excipients solution: Suspend an amount of the placebo mixture equivalent to the weight of the excipients in one dosage unit and one empty Capsule shell in 900 mL of *Medium*. Heat to 37°, and filter.

Analysis

Samples: *Medium*, *Standard solution*, *Sample solution*, and *Excipients solution*

Determine the amount of oseltamivir phosphate ($C_{16}H_{28}N_2O_4 \cdot H_3PO_4$) dissolved by measuring the absorbance at about 240 nm of the *Sample solution* and *Excipients solution* in comparison with the *Standard solution*, using the *Medium* as the blank. Calculate the percentage of oseltamivir phosphate dissolved:

$$\text{Result} = [(A_U - A_E) \times C_S \times V \times 100] / (A_S \times L)$$

A_U = absorbance of the *Sample solution*

A_E = absorbance of the *Excipients solution*

C_S = concentration of [USP Oseltamivir Phosphate RS](#) in the *Standard solution*

V = volume of *Medium*, 900 mL

A_S = absorbance of the *Standard solution*

L = label claim for oseltamivir phosphate (mg/Capsule)

Tolerances: NLT 75% (Q) of the labeled amount of oseltamivir phosphate is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 500 mL, deaerated

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 6.8 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with 8 N [potassium hydroxide](#) solution to a pH of 6.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (25:75)

Standard solution: ($L/500$) mg/mL of oseltamivir from [USP Oseltamivir Phosphate RS](#) in *Medium*, where L is the label claim in mg/Capsule.

Sonicate to dissolve, if necessary.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 207 nm

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

Column temperature: 50°

Flow rate: 1.2 mL/min

Injection volume: 15 µL

Run time: NLT 1.5 times the retention time of oseltamivir

System suitability