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Topiramate Tablets

DEFINITION

Topiramate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$).

IDENTIFICATION

Change to read:

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

Wavenumber range: 4000–650 cm^{-1}

Standard solution: 20 mg/mL of [USP Topiramate RS](#) in acetone

Sample solution: Grind an appropriate number of Tablets to prepare a 20-mg/mL topiramate solution in acetone. Shake the solution for 30 min, and centrifuge for 10 min. Then pass an aliquot of the clear supernatant through a suitable nylon filter of 0.45- μm pore size, and use the filtrate for analysis.

Analysis: Apply 50 μL of the *Standard solution* to a sodium chloride plate, allow the solution to dry, and then obtain the IR spectrum. Wash the window with acetone, and repeat the same procedure using the *Sample solution*.

- **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

Buffer: 1.54 g/L of ammonium acetate in water. Adjust with glacial acetic acid to a pH of 4.0.

Diluent: Methanol and water (1:4)

Mobile phase: Methanol and *Buffer* (1:4)

Standard solution: 6 mg/mL of [USP Topiramate RS](#) in *Diluent*

Sample solution: 6 mg/mL of topiramate in *Diluent* from NLT 12 Tablets, based on the label claim. [NOTE—Shake vigorously for at least 30 min, and pass a portion through a chemical-resistant filter (PTFE) of 0.45- μm pore size.]

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 4.6-mm $\times$ 25-cm; 5- μm packing L1

Temperature

Column: 35°

Detector: 35°

Flow rate: 1.5 mL/min

Injection size: 100 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of topiramate ($C_{12}H_{21}NO_8S$) in the portion of Tablets 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 Topiramate RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of topiramate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Mobile phase: 0.1% trifluoroacetic acid in water and methanol (1:1)

Standard solution: 0.1 mg/mL of [USP Topiramate RS](#) in *Medium*

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

Chromatographic system

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

Mode: LC

Detector: Refractive index

Guard column: 4.0-mm $\times$ 1-cm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L11

Temperature

Column: 40°

Detector: 40°

Flow rate: 1.2 mL/min

Injection size: 100 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of topiramate ($C_{12}H_{21}NO_8S$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s/L) \times V \times 100$$

r_u = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of topiramate is dissolved.

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

Medium: Water; 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 40 min

Standard solution: ($L/900$) mg/mL of [USP Topiramate RS](#) in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first few mL.

Mobile phase: Water and acetonitrile (1:1)

Chromatographic system

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

Mode: LC