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# Topiramate Extended-Release Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-topiramate-erc-20250131.

## DEFINITION

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

## IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K

  **Sample for *Infrared Spectroscopy* 197K:** Grind the contents of Capsules (NLT 20). Transfer an amount of powder equivalent to 250 mg of topiramate to a 250-mL separating funnel. Add 50 mL of 10% alcohol and shake for 5 min. Add 50 mL of chloroform and extract for 10 min, and allow the layers to separate. Filter the chloroform layer through anhydrous sodium sulfate. Evaporate the chloroform to dryness. Use the dry residue.

  **Acceptance criteria:** The spectrum obtained from the *Sample* shows bands at approximately 3383 $cm^{-1}$, 3111 $cm^{-1}$, 2941 $cm^{-1}$, 2908 $cm^{-1}$, 1377 $cm^{-1}$, 1186 $cm^{-1}$, and 1072 $cm^{-1}$, similar to the spectrum from the *Standard* similarly obtained. Peak positions may vary slightly (within ±10 $cm^{-1}$). [Note—Other peaks may be present in the spectra that do not appear in this list.]

- **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.

  **Mobile phase:** Methanol and *Buffer* (40:60)

  **Diluent:** Acetonitrile and water (30:70)

  **Standard solution:** 2 mg/mL of USP Topiramate RS in *Diluent*. Sonicate to dissolve.

  **Sample solution:** Nominally 2 mg/mL of topiramate in *Diluent* prepared as follows. Transfer a suitable quantity of topiramate from the contents of Capsules (NLT 20) to a suitable volumetric flask. Add 60% of the final volume of *Diluent* and sonicate with occasional shaking for NLT 10 min. Allow the solution to cool at room temperature and dilute with *Diluent* to volume. Pass a portion of this solution through a suitable filter of 0.45-µm or finer pore size, discarding NLT the first 1 mL of filtrate.

  **Chromatographic system**

  (See *Chromatography ⟨621⟩, System Suitability*.)

  **Mode:** LC

  **Detector:** Refractive index

  **Column:** 4.6-mm × 10-cm; 5-µm packing L1

  **Temperatures**

  **Column:** 35°

  **Detector:** 35°

  **Flow rate:** 1 mL/min

  **Injection volume:** 40 µL

  **Run time:** NLT 1.5 times the retention time of topiramate

  **System suitability**

  **Sample:** *Standard solution*

  **Suitability requirements**

  **Tailing factor:** NMT 2.0

  **Relative standard deviation:** NMT 1.0%

  **Analysis**

  **Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) in the portion of Capsules taken:

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

$r_U$ = peak response of topiramate from the *Sample solution*

$r_S$ = peak response of topiramate 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**

***Change to read:***

• **Dissolution** ⟨711⟩

**Test 1**

**Medium:** 0.05 M phosphate buffer, pH 7.5 (dissolve 6.8 g of monobasic potassium phosphate in 1 L of water; adjust with 10% sodium hydroxide to a pH of 7.5); 750 mL

**Apparatus 2:** 50 rpm. Use a suitable sinker, if necessary.

**Times:** 2, 4, 8, and 12 h

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

**Mobile phase:** Methanol and *Buffer* (40:60)

**Standard stock solution:** 1.7 mg/mL of USP Topiramate RS prepared as follows. Transfer a suitable amount of USP Topiramate RS to a suitable volumetric flask. Add 10% of the flask volume of acetonitrile and sonicate to dissolve. Dilute with *Medium* to volume.

**Standard solution:** (*L*/750) mg/mL of USP Topiramate RS in *Medium*, from the *Standard stock solution*, where *L* is the label claim in mg/Capsule

**Sample solution:** At the times specified, withdraw a known volume of the solution under test and pass it through a suitable filter of 0.45-µm or finer pore size, discarding NLT the first 5 mL of filtrate. Replace the volume withdrawn with an equal volume of fresh *Medium*.

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm × 10-cm; 5-µm packing L1

**Temperatures**

**Column:** 35°

**Detector:** 35°

**Flow rate:** 1 mL/min

**Injection volume:** 100 µL

**Run time:** NLT 1.5 times the retention time of topiramate

**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 concentration ($C_i$) of topiramate ($C_{12}H_{21}NO_8S$) in the sample withdrawn from the vessel at each time point (*i*):

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

$r_U$ = peak response of topiramate from the *Sample solution*

$r_S$ = peak response of topiramate from the *Standard solution*

$C_S$ = concentration of USP Topiramate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at each time point (*i*):

$$Result_1 = C_1 \times V \times (1/L) \times 100$$

$$Result_2 = [(C_2 \times V) + (C_1 \times V_S)] \times (1/L) \times 100$$

$$Result_3 = \{(C_3 \times V) + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$Result_4 = \{(C_4 \times V) + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$C_i$ = concentration of topiramate in the portion of sample withdrawn at time point *i* (mg/mL)

$V$ = volume of *Medium*, 750 mL

$L$ = label claim (mg/Capsule)

$V_S$ = volume of the *Sample solution* withdrawn at each time point (mL)

**Tolerances:** See *Table 1*.

**Table 1**

| Time Point (*i*) | Time (h) | Amount Dissolved (%) |
|---|---|---|
| 1 | 2 | 22–47 |
| 2 | 4 | 48–73 |
| 3 | 8 | 70–90 |
| 4 | 12 | NLT 80 |

The percentages of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

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

**Medium:** Tris buffer, pH 7.2 (1.18 g/L of tris(hydroxymethyl)aminomethane and 6.35 g/L of tris(hydroxymethyl)aminomethane hydrochloride in water); 900 mL

**Apparatus 1:** 100 rpm

**Times:** 1, 2, and 6 h

**Mobile phase:** Methanol and water (45:55)

**Standard solution:** 0.22 mg/mL of USP Topiramate RS in *Medium*. Sonicate to dissolve, if necessary.

**Sample solution:** At the times specified, pass a portion of the solution under test through a suitable filter of 10-µm pore size.

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Columns**

**Guard:** 3.0-mm × 4-mm; packing L87

**Analytical:** 4.6-mm × 15-cm; 4-µm packing L87

**Temperatures**

**Column:** 35°

**Detector:** 35°

**Flow rate:** 1.5 mL/min

**Injection volume:** 75 µL

**Run time:** NLT 2 times the retention time of topiramate

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 1.5

**Relative standard deviation:** NMT 2.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the concentration ($C_i$) of topiramate ($C_{12}H_{21}NO_8S$) in the sample withdrawn from the vessel at each time point (*i*):

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

$r_U$ = peak response of topiramate from the *Sample solution*

$r_S$ = peak response of topiramate from the *Standard solution*

$C_S$ = concentration of USP Topiramate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at each time point (*i*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$\text{Result}_3 = (\{C_3 \times [V - (2 \times V_S)]\} + [(C_2 + C_1) \times V_S]) \times (1/L) \times 100$$

$C_i$ = concentration of topiramate in the portion of sample withdrawn at time point *i* (mg/mL)

$V$ = volume of *Medium*, 900 mL

$L$ = label claim (mg/Capsule)

$V_S$ = volume of the *Sample solution* withdrawn at each time point (mL)

**Tolerances:** See *Table 2*.

**Table 2**

| Time Point (*i*) | Time (h) | Amount Dissolved (%) |
|---|---|---|
| 1 | 1 | 15–35 |
| 2 | 2 | 39–59 |
| 3 | 6 | NLT 80 |

The percentages of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

▲**Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*

**Medium:** 0.05 M phosphate buffer, pH 7.5 (dissolve 6.8 g of potassium phosphate, monobasic in 1 L water, and add to this solution 7.6 mL of 5 N sodium hydroxide solution; adjust with 1 N hydrochloric acid or 1 N sodium hydroxide solution to a pH of 7.5); 750 mL, deaerated

**Apparatus 2:** 50 rpm

**Times:** 1, 6, and 20 h

**Buffer:** Dissolve 1.54 g of ammonium acetate in 1 L water. Adjust with acetic acid, glacial to a pH of 4.0

**Mobile phase:** Acetonitrile and *Buffer* (46:54)

**Standard stock solution:** 2.222 mg/mL of USP Topiramate RS prepared as follows. Transfer an appropriate quantity of USP Topiramate RS to a suitable volumetric flask, add 40% of the flask volume of acetonitrile and dissolve. Dilute with water to volume.

**Standard solution**

**For Capsules labeled to contain 25 and 50 mg:** 0.067 mg/mL of USP Topiramate RS from *Standard stock solution* in *Medium*

**For Capsules labeled to contain 100 and 200 mg:** 0.267 mg/mL of USP Topiramate RS from *Standard stock solution* in *Medium*

**Sample solution:** At the times specified, withdraw a portion of the solution under test without replacing the withdrawn volume. Pass the solution through a suitable filter of 10-µm pore size.

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Temperatures**

**Column:** 40°

**Detector:** 40°

**Flow rate:** 1 mL/min

**Injection volume:** 100 µL

**Run time:** NLT 1.5 times the retention time of topiramate

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Relative standard deviation:** NMT 5%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the concentration ($C_i$) of topiramate ($C_{12}H_{21}NO_8S$) in the sample withdrawn from the vessel at each time point (*i*):

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

$r_U$ = peak response of topiramate from the *Sample solution*

$r_S$ = peak response of topiramate from the *Standard solution*

$C_S$ = concentration of USP Topiramate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at each time point (*i*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$\text{Result}_3 = (\{C_3 \times [V - (2 \times V_S)]\} + [(C_2 + C_1) \times V_S]) \times (1/L) \times 100$$

$C_i$ = concentration of topiramate in the portion of sample withdrawn at time point *i* (mg/mL)

$V$ = volume of *Medium*, 750 mL

$L$ = label claim (mg/Capsule)

$V_S$ = volume of the *Sample solution* withdrawn at each time point (mL)

**Tolerances:** See *Table 3*.

**Table 3**

| Time Point (*i*) | Time (h) | Amount Dissolved (for Capsules labeled to contain 25 mg) (%) | Amount Dissolved (for Capsules labeled to contain 50, 100, and 200 mg) (%) |
|---|---|---|---|
| 1 | 1 | 10–30 | 10–30 |
| 2 | 6 | 45–65 | 40–60 |
| 3 | 20 | NLT 80 | NLT 80 |

The percentages of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

**Test 4:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*

**Medium:** Tris buffer, pH 7.2 (dissolve 6 g of tris(hydroxymethyl)aminomethane in 1 L of water; adjust with 1 M hydrochloric acid to a pH of 7.2); 900 mL, deaerated

**Apparatus 1:** 100 rpm

**Times:** 1, 2, and 6 h

**Buffer:** Dissolve 1.54 g of ammonium acetate in 1 L water. Adjust with acetic acid, glacial to a pH of 4.0

**Mobile phase:** Methanol and *Buffer* (40:60)

**Standard stock solution:** 1.12 mg/mL of USP Topiramate RS prepared as follows. Transfer an appropriate quantity of USP Topiramate RS to a suitable volumetric flask, add 10% of the flask volume of acetonitrile. Sonicate to dissolve, if necessary. Dilute with *Medium* to volume.

**Standard solution:** (*L*/900) mg/mL of USP Topiramate RS from *Standard stock solution* in *Medium*, where *L* is the label claim in mg/Capsule

**Sample solution:** At the times specified, withdraw a portion of the solution and replace with equal volumes of fresh portions of *Medium* maintained at 37°. Pass the solution through a suitable filter of 0.45-µm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained.

**Chromatographic system**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm × 10-cm; 5-µm packing L1

**Temperatures**

**Column:** 35°

**Detector:** 35°

**Flow rate:** 1 mL/min

**Injection volume:** 100 µL

**Run time:** NLT 1.6 times the retention time of topiramate

**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 concentration ($C_i$) of topiramate ($C_{12}H_{21}NO_8S$) in the sample withdrawn from the vessel at each time point (*i*):

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

$r_U$ = peak response of topiramate from the *Sample solution*

$r_S$ = peak response of topiramate from the *Standard solution*

$C_S$ = concentration of USP Topiramate RS in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at each time point (*i*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = [(C_2 \times V) + (C_1 \times V_S)] \times (1/L) \times 100$$

$$\text{Result}_3 = \{(C_3 \times V) + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$C_i$ = concentration of topiramate in the portion of sample withdrawn at time point *i* (mg/mL)

$V$ = volume of *Medium*, 900 mL

$L$ = label claim (mg/Capsule)

$V_S$ = volume of the *Sample solution* withdrawn at each time point and replaced with *Medium* (mL)

**Tolerances:** See *Table 4*.

**Table 4**

| Time Point (*i*) | Time (h) | Amount Dissolved (%) |
|---|---|---|
| 1 | 1 | 15–35 |
| 2 | 2 | 31–51 |
| 3 | 6 | NLT 80 |

The percentages of the labeled amount of topiramate ($C_{12}H_{21}NO_8S$) dissolved at the times specified conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.▲ (RB 1-Feb-2025)

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

**IMPURITIES**

***Change to read:***

• **Limit of Sulfamate and Sulfate**

**Solution A:** 8 mL of 50% sodium hydroxide solution in 1000 mL of water

**Solution B:** Water

**Solution C:** *Solution A* and *Solution B* (50:50)

**Diluent:** Acetonitrile and water (20:80)

**Mobile phase:** See ▲*Table 5*.▲ (RB 1-Feb-2025)

[Note—It is recommended to use suitable anion trapping techniques to ensure the *Mobile phase* is free of all anionic impurities.]

**▲Table 5▲** (RB 1-Feb-2025)

| Time (min) | Solution A (%) | Solution B (%) | Solution C (%) |
|---|---|---|---|
| 0 | 0 | 95 | 5 |
| 7 | 0 | 95 | 5 |
| 15 | 20 | 0 | 80 |
| 20 | 20 | 0 | 80 |
| 20.1 | 0 | 95 | 5 |
| 30 | 0 | 95 | 5 |

**Standard solution:** 0.037 mg/mL of sodium sulfate and 0.025 mg/mL of sulfamic acid in *Diluent*

**Sample solution:** Nominally 10 mg/mL of topiramate in *Diluent* prepared as follows. Crush the contents of Capsules (NLT 20) and mix. Transfer a suitable quantity of mixed contents to a suitable volumetric flask. Add 60% of the final volume of *Diluent*, sonicate with occasional shaking for NLT 60 min, and dilute with *Diluent* to volume. Pass a portion of this solution through a suitable filter, discarding NLT the first 1 mL of filtrate.

**Chromatographic system**

(See *Chromatography* ⟨621⟩, *System Suitability*.)

**Mode:** LC

**Detector:** Conductivity with suppression

**Columns**

**Guard:** 4-mm × 5-cm; 13-µm packing L81

**Analytical:** 4-mm × 25-cm; 9-µm packing L81

**Detector temperature:** 35°

**Flow rate:** 2 mL/min

**Injection volume:** 50 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—Identify the components using the *Standard solution*. The elution order is the sulfamate peak, followed by the sulfate peak.]

**Suitability requirements**

**Relative standard deviation:** NMT 10.0% for sulfamate and sulfate

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of sulfamate 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 of sulfamate from the *Sample solution*

$r_S$ = peak response of sulfamate from the *Standard solution*

$C_S$ = concentration of sulfamic acid in the *Standard solution* (mg/mL)

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

$M_{r1}$ = molecular weight of sulfamate anion, 96.09

$M_{r2}$ = molecular weight of sulfamic acid, 97.09

Calculate the percentage of sulfate 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 of sulfate from the *Sample solution*

$r_S$ = peak response of sulfate from the *Standard solution*

$C_S$ = concentration of sodium sulfate in the *Standard solution* (mg/mL)

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

$M_{r1}$ = molecular weight of sulfate anion, 96.04

$M_{r2}$ = molecular weight of anhydrous sodium sulfate, 142.04

**Acceptance criteria:** NMT 0.25% of sulfamate and NMT 0.25% of sulfate

***Change to read:***

• **ORGANIC IMPURITIES**

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

**Mobile phase:** Methanol and *Buffer* (30:70)

**Diluent:** Acetonitrile and water (30:70)

**System suitability solution:** 20 mg/mL of USP Topiramate RS and 0.1 mg/mL of USP Topiramate Related Compound A RS in *Diluent*. Sonicate to dissolve.

**Standard solution:** 0.1 mg/mL of USP Topiramate RS in *Diluent*. Sonicate to dissolve.

**Sensitivity solution:** 0.01 mg/mL of USP Topiramate RS from *Standard solution* in *Diluent*

**Sample solution:** Nominally 20 mg/mL of topiramate in *Diluent* prepared as follows. Grind the contents of Capsules (NLT 20) and mix. Transfer a suitable quantity of mixed contents to a suitable volumetric flask. Add 60% of the final volume of *Diluent* and sonicate with intermittent shaking for NLT 60 min. Allow the solution to cool at room temperature and dilute with *Diluent* to volume. Pass a portion of this solution through a suitable filter, discarding NLT the first 1 mL of filtrate.

**Chromatographic system**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 4.6-mm × 25-cm; 5-µm packing L1

**Temperatures**

**Column:** 35°

**Detector:** 35°

**Flow rate:** 1 mL/min

**Injection volume:** 100 µL

**System suitability**

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

[NOTE—See ▲*Table 6*▲ (RB 1-Feb-2025) for the relative retention times.]

**Suitability requirements**

**Resolution:** NLT 1.2 between topiramate related compound A and topiramate, *System suitability solution*

**Relative standard deviation:** NMT 10.0%, *Standard solution*

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

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of any degradation product in the portion of Capsules taken:

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

$r_U$ = peak response of any degradation product from the *Sample solution*

$r_S$ = peak response of topiramate 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)

$F$ = relative response factor (see ▲*Table 6*▲ (RB 1-Feb-2025) )

**Acceptance criteria:** See ▲*Table 6*.▲ (RB 1-Feb-2025) The reporting threshold is 0.1%.

**▲Table 6▲** (RB 1-Feb-2025)

| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---|---|---|---|
| Topiramate related compound A | 0.85 | 1.1 | 0.3 |
| Topiramate | 1.00 | — | — |
| Any unspecified degradation product | — | 1.0 | 0.2 |
| Total degradation products | — | — | 0.5 |

## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Store in well-closed containers at controlled room temperature, protected from moisture and light.
- **LABELING:** The labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Topiramate RS

USP Topiramate Related Compound A RS

2,3:4,5-bis-*O*-(1-Methylethylidene)-*β*-D-fructopyranose.

$C_{12}H_{20}O_6$ 260.29

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| TOPIRAMATE EXTENDED-RELEASE CAPSULES | Documentary Standards Support | SM42020 Small Molecules 4 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM42020 Small Molecules 4 |

**Chromatographic Database Information:** Chromatographic Database

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