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Add the following:

▲Torsemide Compounded Oral Suspension

DEFINITION

Torsemide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$).

Prepare Torsemide Compounded Oral Suspension 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Torsemide Tablets, equivalent to[a]	500 mg of torsemide
Sodium Hydroxide (2 N)	Adjust to pH of 8.3
Vehicle: 1:1 mixture of Ora-Sweet SF[b] and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Torsemide 10-mg tablets, Camber, Piscataway, NJ.

[b] Perrigo, Allegan, MI.

Place the *Torsemide Tablets* in a suitable container and triturate to a fine powder. Add a small amount of *Vehicle* and mix well to form a smooth paste. Add a sufficient amount of *Vehicle* to make the container contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container. Add sufficient *Vehicle* to bring to final volume. Shake to mix well. Add *Sodium Hydroxide (2 N)* dropwise to adjust the pH to 8.3.

ASSAY

• **Procedure**

Solution A: 10 mM of monobasic potassium phosphate adjusted with phosphoric acid to a pH of 4

Mobile phase: Methanol and *Solution A* (45:55)

Diluent: 50% methanol in water

Standard solution: Transfer 20 mg of USP Torsemide RS into a 200-mL volumetric flask. Add approximately 150 mL of *Diluent* and sonicate for 15 min, then dilute with *Diluent* to volume.

Sample solution: Transfer 1 mL of Oral Suspension into a 50-mL volumetric flask. Add approximately 40 mL of *Diluent* and sonicate for 15 min, then dilute with *Diluent* to volume. Filter 1 mL of this solution, discard the first 3 drops, then transfer into an HPLC vial.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Temperatures

Autosampler: 4°

Column: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for torsemide is about 9.6 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$) in the portion of Oral Suspension taken:

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

r_U = peak response of torsemide from the *Sample solution*

r_S = peak response of torsemide from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 8.0–9.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant plastic containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator; NMT 30 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Torsemide RS▲ (USP 1-May-2020)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TORSEMIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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