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Torsemide Tablets

DEFINITION

Torsemide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲ **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲_{2S} (USP41)

ASSAY

Change to read:

• PROCEDURE

Buffer: 2.72 g/L of [monobasic potassium phosphate](#) ▲_{2S} (USP41)

Solution A: [Acetonitrile](#) and [methanol](#) (10:90)

Mobile phase: *Buffer* and *Solution A* (50:50). Adjust with diluted [phosphoric acid](#) (1 in 10 v/v) to a pH of 4.0.

Standard solution: 0.4 mg/mL of [USP Torsemide RS](#) prepared as follows. To a quantity of [USP Torsemide RS](#) in a suitable flask, add methanol to 30% of the flask volume and sonicate for NLT 8 min. Add *Buffer* to fill 75% of the flask volume, cool, and dilute with *Mobile phase*. Pass through a membrane filter of 0.45-μm pore size.

Sample solution: Nominally 0.4 mg/mL of torsemide prepared as follows. Place ▲_{2S} (USP41) 40 mg ▲ of torsemide ▲_{2S} (USP41) from NLT 20 powdered Tablets in a 100-mL volumetric flask. Add methanol to 30% of the flask volume and sonicate for NLT 8 min. Add *Buffer* to fill 75% of the flask volume, cool, and dilute with *Mobile phase*. Pass through a membrane filter of 0.45-μm pore size. ▲ The *Sample solution* is not stable at room temperature but is stable for 12 h at 6°. ▲_{2S} (USP41)

Chromatographic system

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

Mode: LC

Detector: UV 288 nm. ▲ For *Identification B*, use a diode array detector in the range of 200–400 nm. ▲_{2S} (USP41)

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

Temperatures

▲ **Autosampler:** 6° ▲_{2S} (USP41)

Column: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

▲ **Run time:** NLT 2 times the retention time of torsemide ▲_{2S} (USP41)

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 percentage of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$) in the portion of Tablets 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%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

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

Apparatus 2: 50 rpm

Time: 15 min

Buffer, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard stock solution: 0.55 mg/mL $\blacktriangle_{2S}$ of [USP Torsemide RS](#) $\blacktriangle_{2S}$ (USP41) prepared as follows. Transfer a quantity of [USP Torsemide RS](#) to a suitable volumetric flask. Add [methanol](#) to 30% of the flask volume and sonicate until dissolved. Add *Buffer* to fill 75% of the flask volume, cool to room temperature, and dilute with *Mobile phase* to volume.

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of (L/900) mg/mL, where L is the label claim in mg/Tablet.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \blacktriangle_{2S} \text{ (USP41)} \times V \times 100$$

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)

L = label claim (mg/Tablet)

$\blacktriangle_{2S}$ (USP41)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of torsemide ($C_{16}H_{20}N_4O_3S$) 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](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.11 mg/mL of [USP Torsemide RS](#) in *Medium*

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of (L/900) mg/mL, where L is the label claim in mg/Tablet.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 285 nm

Cell: 1.0 cm for 5-, 10-, and 20-mg Tablets and 0.1 cm for 100-mg Tablets

Blank: *Medium*