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## Zonisamide Capsules

### DEFINITION

Zonisamide Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of zonisamide ( $C_8H_8N_2O_3S$ ).

### 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.

**Change to read:**

• **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

**Sample solution:** Shake the contents of a sufficient quantity of Capsules, equivalent to about 100 mg of zonisamide, with 5 mL of methanol. Sonicate for 2 min and pass through a filter of 0.45- $\mu$ m pore size or equivalent. Discard the initial 1-mL portion and evaporate the solution at 85°. Cool the residue. Use 1–2 mg of the residue.

**Analysis:** The IR spectrum of the *Sample solution* corresponds to the IR spectrum of similarly prepared [USP Zonisamide RS](#).

### ASSAY

#### • PROCEDURE

**Mobile phase:** Acetonitrile, methanol, and [0.1% trifluoroacetic acid TS](#) (20:16:64)

**Standard stock solution:** 1 mg/mL of [USP Zonisamide RS](#) in methanol

**Standard solution:** 0.1 mg/mL of zonisamide in *Mobile phase*, from the *Standard stock solution*

**Sample stock solution:** Nominally 1.0 mg/mL of zonisamide prepared as follows. Transfer a suitable amount of Capsule contents (NLT 10) to a suitable volumetric flask and add a suitable volume of methanol. Sonicate and shake for 15 min. Dilute with methanol to volume. Alternatively, the *Sample stock solution* can be prepared as follows. Transfer a suitable amount of Capsules (NLT 10) in a suitable volumetric flask, add 20% of the flask volume with [water](#). Stir, and warm slightly for 30 min. Dilute with *Mobile phase* to volume.

**Sample solution:** 0.1 mg/mL of zonisamide in *Mobile phase*, from the *Sample stock solution*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 237 nm

**Column:** 4.6-mm  $\times$  25-cm; 5- $\mu$ m packing [L1](#)

**Column temperature:** 30°

**Flow rate:** 1.0 mL/min

**Injection volume:** 10  $\mu$ L

**Run time:** 1.5 times the retention time of the zonisamide

#### 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 zonisamide ( $C_8H_8N_2O_3S$ ) in the portion of Capsules taken:

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

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

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

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

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

**Acceptance criteria:** 90.0%–110.0%

**Change to read:**

## PERFORMANCE TESTS

### • [DISSOLUTION \(711\)](#)

**Medium:** [Water](#); 900 mL

**Apparatus 2:** ▲75 rpm. Use suitable sinkers, if necessary. ▲ (ERR 1-May-2018)

**Time:** 45 min

Determine the percentage of zonisamide dissolved using one of the following procedures.

### Spectrophotometric procedure

**Standard stock solution:** 0.6 mg/mL of [USP Zonisamide RS](#) in [methanol](#)

**Standard solution:** Dilute the *Standard stock solution* with *Medium* to obtain solutions with final concentrations as given in [Table 1](#).

**Table 1**

| Capsule Strength<br>(mg) | Final Concentration<br>(µg/mL) |
|--------------------------|--------------------------------|
| 25                       | 13                             |
| 50                       | 13                             |
| 100                      | 22                             |

**Sample solution:** 10 mL of the solution under test. Dilute the filtrate with *Medium* as given in [Table 2](#).

**Table 2**

| Capsule Strength<br>(mg) | Volume of<br>Filtrate<br>(mL) | Final Volume<br>(mL) |
|--------------------------|-------------------------------|----------------------|
| 25                       | 5.0                           | 10.0                 |
| 50                       | 5.0                           | 25.0                 |
| 100                      | 5.0                           | 25.0                 |

### Instrumental conditions

**Mode:** UV

**Analytical wavelength:** 241 nm

**Cell:** 1 cm

**Blank:** *Medium*

### Analysis

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

Calculate the percentage of the labeled amount of zonisamide ( $C_8H_8N_2O_3S$ ) dissolved:

$$\text{Result} = (A_u/A_s) \times (C_s/L) \times V \times 100$$

$A_u$  = absorbance from the *Sample solution*

$A_s$  = absorbance from the *Standard solution*

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