

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Aug-2015
 Document Type: USP Monographs
 DocId: GUID-82D57D7D-D3D5-4FE1-977E-D332518CDC8F_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M8852_01_01
 DOI Ref: vu8b7

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Zonisamide Compounded Oral Suspension

DEFINITION

Zonisamide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of zonisamide (C₈H₈N₂O₃S).

Prepare Zonisamide Compounded Oral Suspension 10 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Zonisamide capsules ^a equivalent to	1 g
Vehicle: a 1:1 mixture of Ora-Plus ^b and Ora-Sweet (regular or sugar-free), ^b a sufficient quantity to make	100 mL

^a Zonisamide 100-mg capsules, Mylan, Morgantown, WV.

^b Paddock Laboratories, Minneapolis, MN.

Empty the capsules, and pour the contents into a mortar or other suitable container. Crush the capsule contents into a fine powder using a pestle or other mechanical means. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the mortar contents pourable. Transfer the contents, stepwise and quantitatively, to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume, and mix well. [**CAUTION**—Avoid skin contact or inhalation of zonisamide by using protective gloves and a fume hood or surgical mask.]

ASSAY

• PROCEDURE

Solution A: 50 mM sodium phosphate adjusted with phosphoric acid to a pH of 2.8

Mobile phase: Acetonitrile and *Solution A* (25:75)

Standard stock solution: 1 mg/mL of [USP Zonisamide RS](#) in *Mobile phase*. Sonicate for 10 min.

Standard solution: Transfer 1 mL of the *Standard stock solution* to a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well.

Centrifuge an aliquot of the solution for 10 min at 13,000 rpm.

Sample solution: Shake each bottle of Oral Suspension thoroughly. Transfer 1 mL of Oral Suspension to a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well. Vortex for 30 s, and sonicate for 10 min. Transfer 1 mL of the resultant solution to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume. Centrifuge an aliquot of the solution for 10 min at 13,000 rpm.

Chromatographic system

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

Mode: LC

Detector: UV 264 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing L1

Column temperature: 32°

Flow rate: 1.0 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for zonisamide is about 4.6 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 zonisamide ($C_8H_8N_2O_3S$) 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 zonisamide from the *Sample solution*

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

C_S = concentration of zonisamide in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH (791):** 3.9–4.9

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or 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 Zonisamide RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ZONISAMIDE 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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(2)

Current DocID: GUID-82D57D7D-D3D5-4FE1-977E-D332518CDC8F_1_en-US

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