

Status: Currently Official on 17-Feb-2025  
 Official Date: Official as of 01-May-2020  
 Document Type: USP Monographs  
 DocId: GUID-31440F86-49D3-4D95-A453-87CCAC8AD59A\_2\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M5507\\_02\\_01](https://doi.org/10.31003/USPNF_M5507_02_01)  
 DOI Ref: 2qn8n

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## Zolmitriptan Orally Disintegrating Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb/zolmitriptan-odt-20200424>.

### DEFINITION

Zolmitriptan Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of zolmitriptan ( $C_{16}H_{21}N_3O_2$ ).

### IDENTIFICATION

- **A.** The UV spectrum of the zolmitriptan peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **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:** Dissolve 2 mL of [triethylamine](#) in 1 L of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

**Mobile phase:** [Acetonitrile](#) and *Buffer* (15:85)

**Standard stock solution:** 0.25 mg/mL of [USP Zolmitriptan RS](#) in [methanol](#)

**Standard solution:** 0.025 mg/mL of [USP Zolmitriptan RS](#) in *Mobile phase* from a suitable volume of *Standard stock solution*

**Sample stock solution:** 0.25 mg/mL of zolmitriptan in [methanol](#), prepared as follows. Transfer NLT 20 Tablets to a suitable volumetric flask.

Add 75% of the flask volume of [methanol](#). Sonicate for 30 min. Allow to cool to room temperature and dilute with [methanol](#) to volume.

**Sample solution:** Nominally 0.025 mg/mL of zolmitriptan in *Mobile phase* from a suitable volume of *Sample stock solution*. Pass a portion of the solution under test through a suitable membrane filter of 0.45- $\mu$ m pore size.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 225 nm. For *Identification test A*, use a diode-array detector in the wavelength range of 200–300 nm.

**Column:** 4.6-mm  $\times$  15-cm; 5- $\mu$ m packing [L1](#)

**Column temperature:** 30°

**Flow rate:** 1 mL/min

**Injection volume:** 20  $\mu$ L

**Run time:** NLT 2.5 times the retention time of zolmitriptan

#### 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 zolmitriptan ( $C_{16}H_{21}N_3O_2$ ) in the portion of Tablets taken:

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

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

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

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

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

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

- [DISINTEGRATION \(701\)](#): NMT 30 s

**Change to read:**

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

### ▲Test 1▲ (RB 1-May-2020)

**Medium:** 0.1 N [hydrochloric acid](#); 500 mL

**Apparatus 2:** 50 rpm

**Time:** 15 min

Analyze the sample under test using either the *Chromatographic procedure* or the *Spectroscopic procedure*.▲ (RB 1-May-2020)

#### Chromatographic procedure

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

**Standard solution:** 0.005 mg/mL of [USP Zolmitriptan RS](#) from *Standard stock solution* in *Medium*

**Sample solution:** Pass a portion of the solution under test through a suitable membrane filter of 0.45-μm pore size.

#### Analysis

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

Calculate the percentage of the labeled amount of zolmitriptan ( $C_{16}H_{21}N_3O_2$ ) dissolved:

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

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

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

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

$V$  = volume of *Medium*, 500 mL

$L$  = label claim of zolmitriptan (mg/Tablet)

### ▲Spectroscopic procedure▲ (RB 1-May-2020)

**Standard solution:** 0.01 mg/mL of [USP Zolmitriptan RS](#) from *Standard stock solution* in *Medium*

**Sample solution:** Pass a portion of the solution under test through a suitable membrane filter of 0.2-μm pore size.

#### Instrumental conditions

**Mode:** UV

**Analytical wavelength:** About 283 nm

#### Analysis

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

Calculate the percentage of the labeled amount of zolmitriptan ( $C_{16}H_{21}N_3O_2$ ) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

$A_U$  = absorbance of the *Sample solution*

$A_S$  = absorbance of the *Standard solution*

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

$V$  = volume of *Medium*, 500 mL

$L$  = label claim of zolmitriptan (mg/Tablet)

**Tolerances:** NLT 80% (Q) of the labeled amount of zolmitriptan ( $C_{16}H_{21}N_3O_2$ ) 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](#); 500 mL



**Documents**

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