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# Tizanidine Tablets

## DEFINITION

Tizanidine Tablets contain Tizanidine Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of tizanidine ( $C_9H_8ClN_5S$ ).

## 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.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

## ASSAY

### PROCEDURE

**Solution A:** [Water](#) and [phosphoric acid](#) (44:6)

**Buffer:** 3.5 g/L of [sodium 1-pentanesulfonate](#). Adjust with *Solution A* or [1 N sodium hydroxide](#) to a pH of 3.0.

**Mobile phase:** [Acetonitrile](#) and *Buffer* (20:80)

**Tizanidine related compound A solution:** 0.1 mg/mL of [USP Tizanidine Related Compound A RS](#) in [methanol](#)

**Tizanidine related compound B solution:** 0.1 mg/mL of [USP Tizanidine Related Compound B RS](#) in [methanol](#)

**Tizanidine related compound C solution:** 0.1 mg/mL of [USP Tizanidine Related Compound C RS](#) in [methanol](#)

**System suitability solution:** Transfer 23 mg of [USP Tizanidine Hydrochloride RS](#) to a 100-mL volumetric flask, and add 20 mL of *Mobile phase* and 10 mL each of *Tizanidine related compound A solution*, *Tizanidine related compound B solution*, and *Tizanidine related compound C solution*. Sonicate to dissolve the [USP Tizanidine Hydrochloride RS](#), and dilute with *Mobile phase* to volume.

**Standard solution:** 0.046 mg/mL of [USP Tizanidine Hydrochloride RS](#) in *Mobile phase*

**Sample solution:** Transfer a weighed portion of finely powdered Tablets (NLT 20), equivalent to 20 mg of tizanidine, to a 500-mL volumetric flask. Add 250 mL of *Buffer solution*, sonicate for 15 min with occasional shaking, and shake by mechanical means for 15 min. Add 100 mL of [acetonitrile](#), and mix. Allow to cool, and dilute with *Buffer solution* to volume. Centrifuge a portion of this solution at 2000 rpm or higher for 10 min. Pass a portion of this solution through a filter with a 0.45- $\mu$ m or finer pore size, and use the filtrate.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 230 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

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

**Column temperature:** 50°

**Flow rate:** 1 mL/min

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

### System suitability

**Samples:** *System suitability solution* and *Standard solution*

[NOTE—The relative retention times are listed in [Table 1](#).]

### Suitability requirements

**Resolution:** NLT 4.0 between tizanidine and tizanidine related compound C; NLT 4.0 between tizanidine and tizanidine related compound B, *System suitability solution*

**Tailing factor:** NMT 2.0, *Standard solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

### Analysis

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

Calculate the percentage of the labeled amount of tizanidine ( $C_9H_8ClN_5S$ ) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

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

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

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

$M_{r1}$  = molecular weight of tizanidine, 253.71

$M_{r2}$  = molecular weight of tizanidine hydrochloride, 290.17

**Acceptance criteria:** 90.0%–110.0%

## PERFORMANCE TESTS

### • [DISSOLUTION \(711\)](#)

#### Test 1

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

**Apparatus 1:** 100 rpm

**Time:** 15 min

**Solution A, Buffer, and Mobile phase:** Prepare as directed in the Assay.

**Standard solution:** ( $L/500$ ) mg/mL of [USP Tizanidine Hydrochloride RS](#) in *Medium*, where  $L$  is the label claim, in mg

**Sample solution:** Sample per [Dissolution \(711\)](#). Dilute with *Medium* to a concentration that is similar to the *Standard solution*.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 230 nm

**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)

**Column temperature:** 50°

**Flow rate:** 1 mL/min

**Injection volume:** 20 μL

#### 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 tizanidine ( $C_9H_8ClN_5S$ ) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

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

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

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

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

$L$  = label claim, in mg

$M_{r1}$  = molecular weight of tizanidine, 253.71

$M_{r2}$  = molecular weight of tizanidine hydrochloride, 290.17

**Tolerances:** NLT 80% ( $Q$ ) of the labeled amount of tizanidine ( $C_9H_8ClN_5S$ ) is dissolved.

#### Test 2

[NOTE—If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*.]

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



**Documents**

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