Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2019
Document Type: USP Monographs
DocId: GUID-0E199865-0E5B-48D1-843D-401F415AA6DB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M80842_02_01
DOI Ref: y5lj1

Terazosin Tablets

DEFINITION

Change to read:

Terazosin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ▲anhydrous▲ (USP 1-May-2019) terazosin hydrochloride ($C_{19}H_{25}N_5O_4 \cdot HCl$), calculated as the free base.

IDENTIFICATION

Change to read:

• **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2019)

• **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

Change to read:

• **Procedure**

▲▲ (USP 1-May-2019)

Hydrochloric acid solution: 0.01 N methanolic hydrochloric acid is prepared by adding 0.85 mL of hydrochloric acid to 1 L of methanol.

Diluent: *Hydrochloric acid solution* and water (40:60)

Mobile phase: Acetonitrile and water (70:30). Add 10.00 mL/L of glacial acetic acid, and degas. Pass through a nylon filter of 0.45-µm pore size. Pipet 0.20 mL/L of diethylamine into the solution, and mix.

Standard stock solution: 0.55 mg/mL of USP Terazosin Hydrochloride RS in *Diluent*. Sonicate for 5 min to completely dissolve.

Standard solution: 0.055 mg/mL of USP Terazosin Hydrochloride RS in *Diluent* from the *Standard stock solution*. Pass through a PTFE filter of 0.45-µm pore size, discarding the first few milliliters of filtrate.

Naproxen standard solution: 0.5 mg/mL of USP Naproxen RS, prepared as follows. Dissolve by sonication of USP Naproxen RS in 25% of the volume of the flask of acetonitrile, and dilute with water to volume.

System suitability solution: 0.05 mg/mL of USP Naproxen RS and 0.055 mg/mL of USP Terazosin Hydrochloride RS in *Diluent* from the *Naproxen standard solution* and *Standard stock solution*, respectively. Pass through a PTFE filter of 0.45-µm pore size, discarding the first few milliliters of filtrate.

Sample solution: Nominally 0.05 mg/mL of terazosin in *Diluent*, prepared as follows. ▲Transfer a quantity of NLT 20 Tablets,▲ (USP 1-May-2019) equivalent to 10 mg of terazosin into a 200-mL flask. Add 100 mL of *Diluent*, and sonicate for NLT 10 min. Shake the flask mechanically for NLT 10 min. Repeat until the sample is well dispersed. Allow the solution to cool, and dilute with *Diluent* to volume. Pass through a PTFE filter of 0.45-µm pore size, discarding the first few milliliters of filtrate.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 254 nm.

▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2019)

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 2.5 mL/min

Injection volume: 25 µL

Run time: NLT twice the retention time of terazosin

System suitability

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

[NOTE—▲The relative retention times for naproxen and terazosin are 0.7 and 1.0, respectively.▲ (USP 1-May-2019)]

Suitability requirements

Resolution: NLT 2.0 between naproxen and terazosin, *System suitability solution*

Tailing factor: NMT 1.8 for terazosin, *System suitability solution*

Relative standard deviation: NMT 2.0, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of terazosin ($C_{19}H_{25}N_5O_4$) 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 of terazosin from the *Sample solution*

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

C_S = concentration of ▲USP Terazosin Hydrochloride RS▲ (USP 1-May-2019) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of terazosin, ▲387.44▲ (USP 1-May-2019)

M_{r2} = molecular weight of ▲anhydrous▲ (USP 1-May-2019) terazosin hydrochloride, ▲423.90▲ (USP 1-May-2019)

Acceptance criteria: 90.0%–110.0%, calculated as the free base

PERFORMANCE TESTS

Change to read:

• **DISSOLUTION** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 0.006 mg/mL of USP Terazosin Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution through a suitable filter of 0.45-µm pore size. Dilute with *Medium* to a concentration similar to that of the *Standard solution*, assuming complete dissolution of the label claim.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: UV 245 nm

Cell length: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of terazosin ($C_{19}H_{25}N_5O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_{r1}/M_{r2}) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* ▲(mg/mL)▲ (USP 1-May-2019)

L = label claim (mg/Tablet)

M_{r1} = molecular weight of terazosin, ▲387.44▲ (USP 1-May-2019)

M_{r2} = molecular weight of ▲anhydrous▲ (USP 1-May-2019) terazosin hydrochloride, ▲423.90▲ (USP 1-May-2019)

V = volume of *Medium*, 900 mL

Tolerances: NLT 75% (*Q*) of the labeled amount of terazosin ($C_{19}H_{25}N_5O_4$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

Buffer: Dissolve 4.1 g of monobasic potassium phosphate and 1.1 g of sodium 1-heptanesulfonate monohydrate in 950 mL of water. Adjust with phosphoric acid to a pH of 3.0 ± 0.10. Dilute with water to 1 L. Pass through a ▲suitable▲ (USP 1-May-2019) filter of 0.45-µm pore size.

Mobile phase: Acetonitrile and *Buffer* (24:76)

Standard solution: 0.003 mg/mL of ▲▲ (USP 1-May-2019) USP Terazosin Hydrochloride RS in *Mobile phase*

Sensitivity solution: 0.15 µg/mL of USP Terazosin Hydrochloride RS in *Mobile phase* from the *Standard solution*

Sample solution: ▲Nominally 0.3 mg/mL of terazosin in *Mobile phase*, prepared as follows. Transfer a portion of the powder from the crushed Tablets (NLT 20), equivalent to 15 mg of terazosin, into a 50-mL volumetric flask.▲ (USP 1-May-2019) Dilute with *Mobile phase* to approximately half the volume of the flask. Sonicate for NLT 10 min, and shake the flask for NLT 20 min. Dilute with *Mobile phase* to volume, and pass through a ▲suitable▲ (USP 1-May-2019) filter of 0.45-µm pore size, discarding the first 5 mL of filtrate.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 246 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

▲▲ (USP 1-May-2019)

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: ▲NLT 4.5 times the retention time of terazosin▲ (USP 1-May-2019)

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Capacity factor, *k'*: NLT 1.0, *Standard solution*

Tailing factor: NMT 2.0, *Standard solution*

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

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each ▲specified and unspecified degradation product▲ (USP 1-May-2019) in the portion of Tablets taken:

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

r_U = peak response of each individual ▲degradation product▲ (USP 1-May-2019) from the *Sample solution*

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

C_S = concentration of ▲USP Terazosin Hydrochloride RS▲ (USP 1-May-2019) in the *Standard solution* (mg/mL)

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

F = relative response factor (see *Table 1*)

M_{r1} = molecular weight of terazosin, ▲387.44▲ (USP 1-May-2019)

M_{r2} = molecular weight of ▲anhydrous▲ (USP 1-May-2019) terazosin hydrochloride, ▲423.90▲ (USP 1-May-2019)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Terazosin related compound A▲ (USP 1-May-2019) [a]	0.52	1.1	0.4
▲Terazosin	1.0	1.0	—▲ (USP 1-May-2019)
▲Doxazosin related compound C▲ (USP 1-May-2019) [b]	1.37	1.2	0.4
▲Terazosin related compound C▲ (USP 1-May-2019) [c]	3.85	1.0	0.4
Any ▲unspecified degradation product▲ (USP 1-May-2019)	—	▲1.0▲ (USP 1-May-2019)	0.2
Total ▲degradation products▲ (USP 1-May-2019)	—	—	1.2

▲[a] 6,7-Dimethoxy-2-(piperazin-1-yl)quinazolin-4-amine dihydrochloride.

[b] 2-Chloro-4-amino-6,7-dimethoxyquinazoline.

[c] 2,2'-(Piperazine-1,4-diyl)bis(6,7-dimethoxyquinazolin-4-amine) dihydrochloride.▲ (USP 1-May-2019)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers protected from moisture and light. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

  USP Naproxen RS

  USP Terazosin Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TERAZOSIN TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(2)

Current DocID: GUID-0E199865-0E5B-48D1-843D-401F415AA6DB_2_en-US

DOI: https://doi.org/10.31003/USPNF_M80842_02_01

DOI ref: y5lj1