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Terazosin Capsules

DEFINITION
Terazosin Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of $C_{19}H_{25}N_5O_4 \cdot HCl$, calculated as the free base.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U

Diluent: 0.1 N hydrochloric acid

Standard solution: 0.005 mg/mL of terazosin hydrochloride from USP Terazosin Hydrochloride RS in *Diluent*. Sonicate for 10 min to completely dissolve. Pass the solution through a nylon filter of 0.45-µm pore size.

Sample solution: Combine the contents from 20 Capsules and transfer 10 mg into a 100-mL flask. Fill with *Diluent* to 50% of the volume of the flask. Sonicate the flask for 10 min. Allow it to cool to room temperature. Dilute with *Diluent* to volume. Further dilute 5 mL of this solution with *Diluent* to 100 mL, and mix well. Pass 10 mL of this preparation through a PTFE filter with a 0.45-µm pore size.

Blank: Pass the *Diluent* through a PTFE filter of 0.45-µm pore size.

• **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**

[Note—Use an all-glass syringe.]

Hydrochloric acid solution: Prepare ▲0.01 N methanolic hydrochloric acid▲ (ERR 1-Oct-2022) by adding 0.85 mL of hydrochloric acid to 1 L of methanol.

Diluent: *Hydrochloric acid solution* and water (2:3)

Mobile phase: Acetonitrile and water (7:3). Pass through a nylon filter of 0.45-µm pore size. Add 10 mL/L of glacial acetic acid, and degas. After degassing, pipet 0.20 mL/L of diethylamine into the solution, and mix.

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

Standard solution: 0.055 mg/mL of terazosin hydrochloride in *Diluent* from *Standard stock solution*. Pass through a PTFE filter of 0.45-µm pore size, discarding NLT the first 8 mL of filtrate.

Sample solution: Combine the contents of NLT 20 Capsules and weigh a quantity 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 8 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

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 the terazosin peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8 for the terazosin peak

Relative standard deviation: NMT 2.0%

Analysis

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Samples: *Standard solution* and *Sample solution*

Calculate the percentage of terazosin ($C_{19}H_{25}N_5O_4$), based on the label claim, in the portion of Capsules 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 terazosin hydrochloride in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of terazosin, 387.43

M_{r2} = molecular weight of terazosin hydrochloride, 423.89

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

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Test 1

Medium: Water; 900 mL

Apparatus 2: 50 rpm, with sinkers, if necessary

Time: 60 min

Standard solution: (387.44/423.89)(L/900) mg/mL of USP Terazosin Hydrochloride RS in *Medium*, where L is the Capsule label claim (terazosin), in mg

Sample solution: At the designated time, withdraw 20 mL of the solution under test, and centrifuge at NMT 3000 rpm for 20 min.

Capsule blank solution: Dissolve 10 empty Capsule shells in 900 mL of *Medium* heated to 37°. Centrifuge a portion of this solution for 20 min.

Spectrometric conditions

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

Mode: UV

Analytical wavelength: UV 246 nm

Cell length: 5 cm for Capsules labeled to contain 1 mg; 1 cm for Capsules labeled to contain 2 or 5 mg; 0.5 cm for Capsules labeled to contain 10 mg

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of terazosin dissolved:

$$\text{Result} = \{[A_U - (A_B/10)]/A_S\} \times C_S/L \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_B = absorbance of the *Capsule blank solution*

A_S = absorbance of the *Standard solution*

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

L = terazosin label claim (mg/Capsule)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of terazosin is dissolved.

Test 2: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*.

Medium: Water; 900 mL

Apparatus 2: 50 rpm, with wire helix sinker.

Time: 30 min

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0.1 M phosphate buffer: 13.6 g/mL of monobasic potassium phosphate and 4 mL/L of triethylamine in water. Adjust with phosphoric acid to a pH of 2.5 ± 0.05.

Mobile phase: Acetonitrile and *0.1 M phosphate buffer* (1:3)

Standard solution: (387.44/423.89)(L/900) mg/mL of USP Terazosin Hydrochloride RS in *Medium*, where L is the Capsule label claim (terazosin), in mg

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

Chromatographic system

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

Mode: LC

Detector: UV 246 nm

Column: 3.9-mm × 30-cm; 10-µm packing L11

Flow rate: 1.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of terazosin dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = terazosin label claim (mg/Capsule)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of terazosin is dissolved.

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

IMPURITIES

Organic Impurities

• **Procedure**

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 nylon filter of 0.45-µm pore size.

Mobile phase: Acetonitrile and *Buffer* (6:19)

Standard solution: 0.003 mg/mL of terazosin hydrochloride from USP Terazosin Hydrochloride RS in *Mobile phase*

Sample solution: Transfer 15 mg of terazosin from the contents of 20 Capsules into a 50-mL volumetric flask. 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 nylon or Teflon filter of 0.45-µm pore size, discarding the first 5 mL of filtrate. The final concentration of the *Sample solution* is 0.3 mg/mL.

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

Chromatographic system

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

Mode: LC

Detector: UV 246 nm

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

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 1.2 times the retention time of terazosin for the *Standard solution* and *Sensitivity solution*; NLT 4.5 times the retention time of terazosin in the *Sample solution*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

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Capacity factor, k': NLT 1.0 for the terazosin peak, *Standard solution*

Tailing factor: NMT 2.0 for the terazosin peak, *Standard solution*

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

Signal-to-noise ratio: NLT 10 for the terazosin peak, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Capsules 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 impurity from the *Sample solution*

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

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

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

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

M_{r1} = molecular weight of terazosin, 387.43

M_{r2} = molecular weight of terazosin hydrochloride, 423.89

Acceptance criteria: See *Impurity Table 1*.

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Piperazinyl-ADMQ[a]	0.52	1.1	0.4
Chloro ADMQ[b]	1.37	1.2	0.4
Bis-ADMQ-piperazine[c]	3.85	1.0	0.4
Any other individual, unspecified impurity	—	—	0.2
Total impurities	—	—	1.2

[a] *N*-(4-Amino-6,7 dimethoxy-2-quinazolinyl)piperazine.

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

[c] *N,N*-Bis-(4-amino-6,7 dimethoxy-2-quinazolinyl)piperazine.

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ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers protected from moisture and light. Store at controlled room temperature.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩
  USP Terazosin Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TERAZOSIN CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2

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

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