

Status: Currently Official on 13-Feb-2025
 Official Date: Official as of 01-May-2022
 Document Type: USP Monographs
 DocId: GUID-CADBAAB6-2C0C-496C-B9CC-93C2C29F654B_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M6335_03_01
 DOI Ref: s10jk

© 2025 USPC
 Do not distribute

Atenolol Tablets

DEFINITION

Atenolol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of atenolol ($C_{14}H_{22}N_2O_3$).

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-2022)

Change to read:

- **B.** The retention time of the ▲major▲ (USP 1-May-2022) peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

▲**0.8 M phosphoric acid solution:** Dilute 5.2 mL of [phosphoric acid](#) in 100 mL of water.

Buffer: 1.1 g of [sodium 1-heptanesulfonate](#); 0.71 g of [sodium phosphate, dibasic, anhydrous](#); and 2 mL of [dibutylamine](#) in 700 mL of [water](#).

Adjust with 0.8 M phosphoric acid solution to a pH of 3.0.▲ (USP 1-May-2022)

Mobile phase: ▲[Methanol](#) and Buffer (30:70)▲ (USP 1-May-2022)

Standard solution: 0.01 mg/mL of [USP Atenolol RS](#) in *Mobile phase*

▲▲ (USP 1-May-2022)

Sample solution: ▲Nominally 0.01 mg/mL of atenolol in *Mobile phase* prepared as follows. Transfer 10 Tablets to a 1000-mL volumetric flask. Add 500 mL of *Mobile phase* and sonicate for 15 min to disintegrate the Tablets. Dilute with *Mobile phase* to volume. Centrifuge a portion of the solution.▲ (USP 1-May-2022) Dilute a volume of the supernatant with *Mobile phase* to obtain a solution nominally containing 0.01 mg/mL of atenolol.

Chromatographic system

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

Mode: LC

Detector: UV 226 nm. ▲For *Identification A*, use a diode array detector in the range of 190–400 nm.▲ (USP 1-May-2022)

Column: 3.9-mm × 30-cm; ▲4-μm▲ (USP 1-May-2022) packing [L1](#)

Flow rate: 0.6 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-May-2022)

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▲ (USP 1-May-2022) atenolol ($C_{14}H_{22}N_2O_3$) in ▲the portion of Tablets▲ (USP 1-May-2022) taken:

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

r_U = peak response of atenolol from the *Sample solution*

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

C_s = concentration of [USP Atenolol RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of atenolol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N acetate buffer, pH 4.6 [prepared by mixing 44.9 parts (v/v) of 0.1 N sodium acetate with 55.1 parts (v/v) of 0.1 N acetic acid solution, and adjust with either diluted sodium hydroxide or diluted acetic acid to a pH of 4.6]; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

▲▲ (USP 1-May-2022)

Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay. ▲▲ (USP 1-May-2022)

Standard solution: 0.01 mg/mL of [USP Atenolol RS](#) in *Mobile phase*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Quantitatively dilute a measured volume of the filtrate with *Mobile phase* to obtain a solution estimated to contain about 0.01 mg/mL of atenolol.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲the labeled amount of ▲ (USP 1-May-2022) atenolol ($C_{14}H_{22}N_2O_3$) dissolved:

$$\text{Result} = (r_u/r_s) \times C_s \times V \times D \times (100/L)$$

r_u = peak response of atenolol from the *Sample solution*

r_s = peak response of atenolol from the *Standard solution*

C_s = concentration of [USP Atenolol RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of atenolol ($C_{14}H_{22}N_2O_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

Add the following:

▲IMPURITIES

• ORGANIC IMPURITIES

Buffer: 3.4 g/L of [potassium phosphate, monobasic](#); 1.25 g/L of [octanesulfonic acid sodium salt](#); and 0.5 g/L of [tetrabutylammonium hydrogen sulfate](#)

0.8 M phosphoric acid solution: Dilute 5.2 mL of [phosphoric acid](#) in 100 mL of [water](#).

Mobile phase: [Methanol](#), [tetrahydrofuran](#), and *Buffer* (18:2:80). Adjust with 0.8 M phosphoric acid solution to a pH of 3.0.

Impurity stock solutions 1–3: 0.1 mg/mL each of [USP Atenolol Related Compound A RS](#), [USP Atenolol Related Compound B RS](#), and [USP Atenolol Related Compound F RS](#) prepared as follows. Separately transfer an appropriate quantity of [USP Atenolol Related Compound A RS](#), [USP Atenolol Related Compound B RS](#), and [USP Atenolol Related Compound F RS](#) to individual suitable volumetric flasks. Add [methanol](#) to 10% of the final volume and sonicate to dissolve. Dilute with *Mobile phase* to volume.

Impurity stock solution 4: 0.1 mg/mL of [USP Atenolol Related Compound E RS](#) prepared as follows. Transfer an appropriate quantity of [USP Atenolol Related Compound E RS](#) to a suitable volumetric flask. Add [acetonitrile](#) to 50% of the final volume and sonicate to dissolve. Dilute with [water](#) to volume.

Sensitivity solution: 0.001 mg/mL of [USP Atenolol RS](#) in *Mobile phase*

Standard solution: 0.01 mg/mL of [USP Atenolol RS](#) and 0.005 mg/mL each of [USP Atenolol Related Compound A RS](#), [USP Atenolol Related Compound B RS](#), [USP Atenolol Related Compound E RS](#), and [USP Atenolol Related Compound F RS](#) from the corresponding *Impurity stock solution* in *Mobile phase*

Sample solution: Nominally 2 mg/mL of atenolol in *Mobile phase* prepared as follows. Transfer an appropriate quantity of atenolol from powdered Tablets (NLT 20) to a suitable volumetric flask. Add *Mobile phase* to 50% of the final volume and sonicate for 15 min to dissolve. Dilute with *Mobile phase* to volume. Pass through a suitable filter of 0.45-μm pore size and discard the first 5 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 226 nm