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Atenolol Injection

» Atenolol Injection is a sterile solution of Atenolol in Water for Injection. It contains a suitable buffering agent. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of atenolol ($C_{14}H_{22}N_2O_3$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, in a cool place or at controlled room temperature, protected from light. Avoid freezing.

USP Reference standards ⟨11⟩—
USP Atenolol RS

Identification—

A: The retention time of the main peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* obtained as directed in the *Assay*.

Change to read:

B: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 10 µg of atenolol per mL.
Medium: methanol.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 33.3 USP Endotoxin Units per mg of atenolol.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 5.5 and 6.5.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Assay—

Citric acid buffer—Transfer 2.5 g of citric acid to a 500-mL volumetric flask, add 400 mL of water, and swirl to dissolve. Adjust the solution with 2 N sodium hydroxide to a pH of 6.0, dilute with water to volume, and mix.

Mobile phase—Dissolve 930 mg of sodium octyl sulfate in 740 mL of water, add 8 mL of 3.6 N sulfuric acid, mix, and pass through a 1-µm or finer porosity filter. To the filtrate add 250 mL of acetonitrile, mix, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Transfer about 50 mg of USP Atenolol RS to a 100-mL volumetric flask, add 80 mL of *Citric acid buffer*, and sonicate for about 30 seconds to achieve dissolution. Dilute with *Citric acid buffer* to volume, and mix. Transfer 4.0 mL of this solution to a 10-mL volumetric flask, dilute with *Citric acid buffer* to volume, and mix. This solution contains about 0.2 mg of USP Atenolol RS per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to 2 mg of atenolol, to a 10-mL volumetric flask, dilute with *Citric acid buffer* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 275-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 1.7 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 2, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of $C_{14}H_{22}N_2O_3$ in each mL of the Injection taken by the formula:

$$10(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Atenolol RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and r_U and r_S are the atenolol peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
ATENOLOL INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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