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Atenolol Compounded Oral Suspension

DEFINITION

Atenolol Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of atenolol ($C_{14}H_{22}N_2O_3$).

Prepare Atenolol Compounded Oral Suspension 10 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Atenolol powder	1 g
Vehicle: a 1:1 mixture of Ora-Plus ^a and Ora-Sweet SF ^a , a sufficient quantity to make	100 mL

^a Perrigo Pharmaceuticals, Allegan, MI.

Pour *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add *Vehicle* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **PROCEDURE**

Solution A: 25 mM sodium phosphate adjusted with phosphoric acid to a pH of 3.0

Solution B: Water adjusted with phosphoric acid to a pH of 3.0

Solution C: Methanol and *Solution B* (50:50)

Mobile phase: Acetonitrile and *Solution A* (15:85). Filter, and degas.

Standard stock solution: 10 mg/mL of [USP Atenolol RS](#) in *Solution C*. Mix well and sonicate for 3 min. Store at 2°–8°.

Standard solution: Transfer 2.0 mL of the *Standard stock solution* to a 500-mL volumetric flask, add 0.5 mL of *Solution C*, and dilute with *Solution B* to volume. Mix well. Centrifuge a portion of the resultant solution for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Sample solution: Shake each bottle of Oral Suspension thoroughly. Transfer 2.0 mL of Oral Suspension into a 500-mL volumetric flask, and add 0.5 mL of *Solution C*. Dilute with *Solution B* to volume. Mix well. Centrifuge a portion of the solution for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Chromatographic system

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

Mode: LC

Detector: UV 227 nm

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

Temperatures

Column: 30°

Autosampler: 5°

Flow rate: 0.7 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for atenolol is about 5.1 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of atenolol ($C_{14}H_{22}N_2O_3$) in the portion of Oral Suspension 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 atenolol in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 6.4–7.4

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.
- **LABELING:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or at controlled room temperature
- **USP REFERENCE STANDARDS (11).**
[USP Atenolol RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ATENOLOL COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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