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Atenolol Compounded Oral Suspension, Veterinary

DEFINITION

Atenolol Compounded Oral Suspension, Veterinary 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, Veterinary 25 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Atenolol powder	2.5 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 the *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *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

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

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

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

Standard stock solution: 25 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 1-L volumetric flask, and add 0.5 mL of *Solution C*. Dilute with *Solution B* to volume, and 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 thoroughly each bottle of Oral Suspension, Veterinary. Transfer 2.0 mL of Oral Suspension, Veterinary to a 1-L volumetric flask, and add 0.5 mL of *Solution C*. Dilute with *Solution B* to volume. 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, Veterinary taken:

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

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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⟩**:** 9.1–10.1

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*. Label it to state that it is for veterinary use only.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or 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, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

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