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Marbofloxacin Compounded Oral Suspension, Veterinary

DEFINITION

Marbofloxacin Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of marbofloxacin ($C_{17}H_{19}FN_4O_4$).

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

Marbofloxacin powder	2.5 g
Purified Water	A small amount
Vehicle: 1:1 mixture of Ora-Plus[a] and Ora-Sweet[a]; or Ora-Blend[a], a sufficient quantity to make	100 mL

[a] Perrigo Pharmaceuticals, Allegan, MI.

Wet the *Marbofloxacin powder* with a small amount of *Purified Water* and triturate to make a smooth paste. Add the *Vehicle* to make the mortar contents pourable. Transfer the contents of the mortar stepwise and quantitatively to a calibrated container using the *Vehicle*. Add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 10 mM ammonium formate containing 0.1% (v/v) formic acid

Solution B: Methanol containing 0.1% formic acid

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
0.5	90	10
23.0	70	30
23.5	70	30
23.6	0	100
26	0	100
26.1	90	10
30	90	10

Standard solution: 0.4 mg/mL of marbofloxacin in *Solution A*

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Sample solution: Transfer 1.6 mL of Oral Suspension, Veterinary to a 100-mL volumetric flask, dilute with *Solution A* to volume, and mix well. Pass through a PVDF filter of 0.2-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 327 nm

Columns

Guard: Packing L1

Analytical: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for marbofloxacin is about 6.2 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 marbofloxacin ($C_{17}H_{19}FN_4O_4$) in the portion of Oral Suspension, Veterinary taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 6.2–7.2

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant, plastic containers. Store in a refrigerator (2°–8°) or at controlled room temperature.

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator (2°–8°) or at controlled room temperature. [NOTE—A slight darkening in yellow color may occur in the suspension with 1:1 Ora-Plus and Ora-Sweet that does not affect the strength of the preparation.]

• **LABELING:** Label it to indicate that it is for veterinary use only. Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

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

Topic/Question	Contact	Expert Committee
MARBOFLOXACIN COMPOUNDED ORAL SUSPENSION, VETERINARY	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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