Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2015
Document Type: USP Monographs
DocId: GUID-4A2F7413-D8F1-4071-A1BD-96AC0DD9AFA1_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8091_01_01
DOI Ref: g5tu6

Enrofloxacin Compounded Oral Suspension, Veterinary

DEFINITION

Enrofloxacin Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of enrofloxacin ($C_{19}H_{22}FN_3O_3$).

Prepare Enrofloxacin Compounded Oral Suspension, Veterinary 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Enrofloxacin powder	2 g
Vehicle: a 1:1 mixture of hypromellose 1% solution and Syrpalta,[a] a sufficient quantity to make	100 mL

[a] Humco, Texarkana, TX.

Prepare a hypromellose 1% solution by heating 25 mL of Purified Water to boiling in a calibrated beaker, and slowly adding 0.5 g of hypromellose with stirring. When the hypromellose is completely dispersed, take the beaker off heat, and add cold Purified Water with continuous stirring until gelled. Add cold Purified Water to bring to a final volume of 50 mL with stirring. Continue mixing until a clear, homogenous solution results. Place the solution in a refrigerator overnight to allow for complete hydration. Prepare the *Vehicle* by mixing equal volumes of the previously prepared hypromellose 1% solution and the *Syrpalta*.

Place the *Enrofloxacin powder* into a suitable mortar. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add sufficient *Vehicle* to make the mortar contents pourable. Transfer the contents of the mortar, 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**

Mobile phase: Acetonitrile and 50 mM phosphoric acid (15:85). Filter, and degas.

System suitability solution: Dissolve about 5 mg of USP Enrofloxacin Related Compound Mixture RS in a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Standard solution: 0.1 mg/mL of enrofloxacin prepared from USP Enrofloxacin RS in *Mobile phase*

Sample solution: Shake thoroughly each bottle of Oral Suspension, Veterinary. Transfer 1 mL of Oral Suspension, Veterinary into a 200-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well. Pass through a PVDF filter of 0.45-µm pore size, discarding the first 3 mL.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 277 nm

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

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for ciprofloxacin and enrofloxacin are 0.76 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between enrofloxacin and ciprofloxacin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0% for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of enrofloxacin ($C_{19}H_{22}FN_3O_3$) 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 enrofloxacin from the *Sample solution*

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

C_S = concentration of USP Enrofloxacin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 6.0–7.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant 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

• **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.

• **USP Reference Standards** ⟨11⟩

USP Enrofloxacin RS

USP Enrofloxacin Related Compound Mixture RS

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

Topic/Question	Contact	Expert Committee
ENROFLOXACIN COMPOUNDED ORAL SUSPENSION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(4)

Current DocID: GUID-4A2F7413-D8F1-4071-A1BD-96AC0DD9AFA1_1_en-US

DOI: https://doi.org/10.31003/USPNF_M8091_01_01

DOI ref: g5tu6