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Add the following:

Chloramphenicol Compounded Oral Suspension, Veterinary

DEFINITION

Chloramphenicol Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 120.0% of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$).

Prepare Chloramphenicol Compounded Oral Suspension, Veterinary 200 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Chloramphenicol tablets, ^a equivalent to	20 g of chloramphenicol
Purified Water	30 mL
Ora-Blend, ^b a sufficient quantity to make	100 mL

- ^a Chloramphenicol 1-g tablets, Bimeda, Inc., Le Seuer, MN.
^b Perrigo, Allegan, MI.

Place the *Chloramphenicol tablets* in a suitable container and cover with *Purified Water*. Allow the tablets to soak for 15–20 min. Add 30 mL of *Ora-Blend* and triturate to a smooth paste. Add a sufficient amount of *Ora-Blend* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume. Shake to mix well.

ASSAY

• PROCEDURE

Solution A: Mix 500 mL of methanol and 600 mL of water. Add 1 mL of glacial acetic acid.

Solution B: Add 0.5 mL of glacial acetic acid to 500 mL of methanol.

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
6	100	0
10	40	60
10	100	0
15	100	0

Standard solution: Transfer 20 mg of [USP Chloramphenicol RS](#) into a 200-mL volumetric flask. Add approximately 160 mL of *Solution A*, sonicate for 5 min, then dilute with *Solution A* to volume.

Sample solution: Transfer 1 mL of Oral Suspension, Veterinary into a 200-mL volumetric flask. Add approximately 160 mL of *Solution A*, sonicate for 15 min, then dilute with *Solution A* to volume. Transfer 1 mL of this solution into a 10-mL volumetric flask. Dilute with *Solution A* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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

Temperatures

Autosampler: 4°

Column: 30°

Flow rate: 1.0 mL/min

Injection volume: 15 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for chloramphenicol is about 6.3 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 chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) 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 chloramphenicol from the *Sample solution*

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

C_S = concentration of [USP Chloramphenicol RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

- [pH \(791\)](#): 4.7–5.7

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator or at controlled room temperature
- **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*.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Chloramphenicol RS](#)
- ▲ (USP 1-May-2020)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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