Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Mar-2019
Document Type: USP Monographs
DocId: GUID-7028F05C-6912-47E5-952A-F781041E9714_5_en-US
DOI: https://doi.org/10.31003/USPNF_M10960_05_01
DOI Ref: tms50



*Add the following:*

# ▲Ivermectin Compounded Oral Solution, Veterinary

## DEFINITION

Ivermectin Compounded Oral Solution, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of ivermectin, calculated as the sum of components $H_2B_{1a}(C_{48}H_{74}O_{14})$ plus $H_2B_{1b}(C_{47}H_{72}O_{14})$.

Prepare Ivermectin Compounded Oral Solution, Veterinary 3 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

| | |
|---|---|
| Ivermectin Injection,[a] equivalent to | 30 mg of ivermectin |
| Polyethylene Glycol 400, a sufficient quantity to make | 10 mL |

[a] Ivomec Injection 1%, Merial Ltd., Duluth, GA.

Accurately measure the *Ivermectin Injection* and place into a suitable container. Add sufficient *Polyethylene Glycol 400* to bring to final volume. Shake to mix well.

## ASSAY

• **Procedure**

**Mobile phase:** Acetonitrile, methanol, and water (45:40:15)

**Standard solution:** 0.12 mg/mL of USP Ivermectin RS in methanol

**Sample solution:** Transfer 1 mL of Oral Solution, Veterinary to a 25-mL volumetric flask, and dilute with methanol to volume.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 245 nm

**Column:** 4.6-mm × 25-cm; 3.6-µm packing L1

**Temperatures**

**Autosampler:** 15°

**Column:** 20°

**Flow rate:** 1 mL/min

**Injection volume:** 25 µL

**System suitability**

**Sample:** *Standard solution*

[Note—The retention times for component $H_2B_{1b}$ and component $H_2B_{1a}$ are about 23.8 and 31.6 min, respectively.]

**Suitability requirements**

**Resolution:** NLT 3.0 between component $H_2B_{1b}$ and component $H_2B_{1a}$

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0% for replicate injections determined from the component $H_2B_{1a}$ peak

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ivermectin components $H_2B_{1a}(C_{48}H_{74}O_{14})$ plus $H_2B_{1b}(C_{47}H_{72}O_{14})$ in the portion of Oral Solution, Veterinary taken:

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

$r_U$ = peak response of $H_2B_{1a}$ plus $H_2B_{1b}$ from the *Sample solution*

$r_S$ = peak response of $H_2B_{1a}$ plus $H_2B_{1b}$ from the *Standard solution*

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

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

**Acceptance criteria:** 90.0%–110.0%

**SPECIFIC TESTS**

• **pH** ⟨791⟩**:** 5.6–6.6

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label to state that it is for veterinary use only and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Ivermectin RS

▲2S *(USP41)*

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| IVERMECTIN COMPOUNDED ORAL SOLUTION, VETERINARY | Brian Serumaga<br>Science Program Manager | CMP2020 Compounding 2020 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | CMP2020 Compounding 2020 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 43(5)

**Current DocID: GUID-7028F05C-6912-47E5-952A-F781041E9714_5_en-US**
**Previous DocID: GUID-7028F05C-6912-47E5-952A-F781041E9714_2_en-US**
**DOI: https://doi.org/10.31003/USPNF_M10960_05_01**
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