Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-B6EA6048-F373-4237-BD38-BE8A90718EA7_1_en-US
DOI: https://doi.org/10.31003/USPNF_M43735_01_01
DOI Ref: hx1eg

Ivermectin Paste

DEFINITION

Ivermectin Paste contains NLT 90.0% and NMT 110.0% of the labeled amount of Ivermectin, calculated as the sum of component H_2B_{1a} ($C_{48}H_{74}O_{14}$) and component H_2B_{1b} ($C_{47}H_{72}O_{14}$). The ratio of the contents, $H_2B_{1a}/(H_2B_{1a} + H_2B_{1b})$, is NLT 90.0%.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Sample solution: 0.5 mg/mL of ivermectin dispersed in methanol from a quantity of Paste. Sonicate if necessary until completely dispersed.

Application volume: 2 µL

Developing solvent system: Methylene chloride, methanol, and ammonium hydroxide (90:9:1)

Analysis: Develop the chromatogram in an unsaturated chamber. Remove the plate, allow to air dry, and examine under short- and long-wavelength UV light.

Acceptance criteria: Meets the requirements

• **B.** The retention times of the two principal component peaks of ivermectin from the *Sample solution* correspond to those of the two principal component peaks of ivermectin from the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and water (106:55:39)

Standard solution: 0.4 mg/mL of USP Ivermectin RS in methanol

Sample solution: Disperse a quantity of Paste in methanol, using sonication if necessary, to obtain a solution containing 0.4 mg/mL of ivermectin.

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

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

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between the first peak (component H_2B_{1b}) and the second peak (component H_2B_{1a})

Relative standard deviation: NMT 2.0%, determined from the component H_2B_{1a} peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ivermectin, component H_2B_{1a} ($C_{48}H_{74}O_{14}$) and component H_2B_{1b} ($C_{47}H_{72}O_{14}$), in the portion of Paste taken:

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

r_U = sum of the peak responses for component H_2B_{1a} and component H_2B_{1b} from the *Sample solution*

r_S = sum of the peak responses for component H_2B_{1a} and component 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)

Calculate the ratio of the contents, in percentage, of the components, $H_2B_{1a}/(H_2B_{1a} + H_2B_{1b})$, in the portion of Paste taken:

$$\text{Result} = (r_U/r_T) \times 100$$

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

r_T = sum of the peak responses for component H_2B_{1a} and component H_2B_{1b} from the *Sample solution*

Acceptance criteria: 90.0%–110.0% of the labeled amount of ivermectin, calculated as the sum of component H_2B_{1a} ($C_{48}H_{74}O_{14}$) and component H_2B_{1b} ($C_{47}H_{72}O_{14}$). The ratio of the contents, $H_2B_{1a}/(H_2B_{1a} + H_2B_{1b})$, is NLT 90.0%.

IMPURITIES

• **Organic Impurities**

Mobile phase, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: 0.004 mg/mL of USP Ivermectin RS in methanol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Paste taken, disregarding any peak below 0.05%:

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

r_U = peak response for each impurity from the *Sample solution*

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

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

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

Acceptance criteria: NMT 3.0% of any peak with a relative retention time of 1.3–1.5, relative to that of the principal peak

Any other impurity: NMT 1.0%

Total impurities: NMT 6.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at a temperature not higher than 30°.

• **Labeling:** Label it to indicate that it is for oral veterinary use only.

• **USP Reference Standards ⟨11⟩**

USP Ivermectin RS

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

Topic/Question	Contact	Expert Committee
IVERMECTIN PASTE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 33(5)

Current DocID: GUID-B6EA6048-F373-4237-BD38-BE8A90718EA7_1_en-US

DOI: https://doi.org/10.31003/USPNF_M43735_01_01

DOI ref: hx1eg