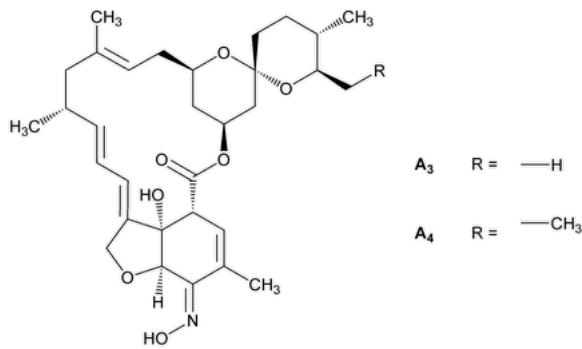


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Milbemycin Oxime

Change to read:



Mixture of milbemycin A₃ oxime and milbemycin A₄ oxime CAS RN®: 129496-10-2.

Milbemycin A₃ OximeC₃₁H₄₃NO₇ ▲541.69

Milbemycin B, 5-demethoxy-28-deoxy-6,28-epoxy-5-(hydroxyamino)-25-methyl-, (6*R*,25*R*)-; (2*R*,2*a'**E*,2*a*1'*S*,4'*E*,5*S*,6*R*,6'*R*,8'*E*,11'*R*,15'*S*,17*a'**R*,20'*Z*,20*a'**R*)-2*a*1'-Hydroxy-20'-(hydroxyimino)-5,6,6',8',19'-pentamethyl-2*a*1',3,4,5,6,6',7',10',11',14',15',17*a'*,20',20*a'*-tetradecahydro-2'*H*,17'*H*-spiro[pyran-2,13'-[11,15]methano[1,5]dioxacyclooctadecino[9,8,7-*cd*]benzofuran]-17'-one.▲ (ERR 1-Jun-2023)

Milbemycin A₄ Oxime

C₃₂H₄₅NO₇ ▲555.71

Milbemycin B, 5-demethoxy-28-deoxy-6,28-epoxy-25-ethyl-5-(hydroxyamino)-, [6*R*,25*R*]-; (2*R*,2*a'**E*,2*a*1'*S*,4'*E*,5*S*,6*R*,6'*R*,8'*E*,11'*R*,15'*S*,17*a'**R*,20'*Z*,20*a'**R*)-6-Ethyl-2*a*1'-hydroxy-20'-(hydroxyimino)-5,6,8',19'-tetramethyl-2*a*1',3,4,5,6,6',7',10',11',14',15',17*a'*,20',20*a'*-tetradecahydro-2'*H*,17'*H*-spiro[pyran-2,13'-[11,15]methano[1,5]dioxacyclooctadecino[9,8,7-*cd*]benzofuran]-17'-one.▲ (ERR 1-Jun-2023)

DEFINITION

Milbemycin Oxime is a mixture of milbemycin A₄ oxime and milbemycin A₃ oxime. It contains NLT 95.0% and NMT 102.0% of the sum of milbemycin A₄ oxime and milbemycin A₃ oxime, calculated on the anhydrous basis. The ratio of milbemycin A₄ oxime is NLT 0.75.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K**
- **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: Water

Solution B: Methanol

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	26	74
2	26	74
27	24.5	75.5

Time (min)	Solution A (%)	Solution B (%)
47	24.5	75.5
47.1	26	74
60	26	74

Diluted phosphoric acid solution: 0.3–0.5 mL/L of phosphoric acid in water

Diluent: Acetonitrile and *Diluted phosphoric acid solution* (75:25)

Standard solution: 0.2 mg/mL of [USP Milbemycin Oxime RS](#) in *Diluent*. Sonicate if necessary to facilitate dissolution.

Sample solution: 0.2 mg/mL of Milbemycin Oxime in *Diluent*. Sonicate if necessary to facilitate dissolution. This solution must be stored at 5° protected from light.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 3.0-mm × 10-cm; 3-μm packing L1

Column temperature: 35°

Flow rate: 0.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—The elution order is milbemycin A₃ oxime followed by milbemycin A₄ oxime. (See [Table 2](#) for the relative retention times.)]

Suitability requirements

Resolution: NLT 9 between milbemycin A₃ oxime and milbemycin A₄ oxime

Tailing factor: NMT 2.0 each for milbemycin A₃ oxime and milbemycin A₄ oxime

Relative standard deviation: NMT 0.73% each for milbemycin A₃ oxime and milbemycin A₄ oxime

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of milbemycin A₃ oxime (C₃₁H₄₃NO₇) in the portion of Milbemycin Oxime taken:

$$\text{Result} = (r_U/r_S) \times [(C_S \times F_{A3})/C_U] \times 100$$

r_U = peak response of milbemycin A₃ from the *Sample solution*

r_S = peak response of milbemycin A₃ from the *Standard solution*

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

F_{A3} = potency of milbemycin A₃ oxime in [USP Milbemycin Oxime RS](#) (mg/mg)

C_U = concentration of Milbemycin Oxime in the *Sample solution* (mg/mL)

Calculate the percentage of milbemycin A₄ oxime (C₃₂H₄₅NO₇) in the portion of Milbemycin Oxime taken:

$$\text{Result} = (r_U/r_S) \times [(C_S \times F_{A4})/C_U] \times 100$$

r_U = peak response of milbemycin A₄ from the *Sample solution*

r_S = peak response of milbemycin A₄ from the *Standard solution*

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

F_{A4} = potency of milbemycin A₄ oxime in [USP Milbemycin Oxime RS](#) (mg/mg)

C_U = concentration of Milbemycin Oxime in the *Sample solution* (mg/mL)

Calculate the percentage of the sum of milbemycin A₃ oxime and milbemycin A₄ oxime in the portion of Milbemycin Oxime taken:

$$\text{Result} = P_{A3} + P_{A4}$$

P_{A3} = percentage of milbemycin A₃ oxime