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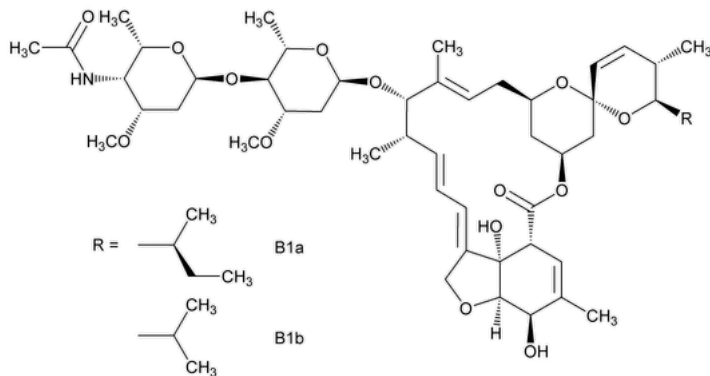
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Eprinomectin


 $C_{50}H_{75}NO_{14}$ (Component B_{1a}) 914.13

 $C_{49}H_{73}NO_{14}$ (Component B_{1b}) 900.10
Component B_{1a}Avermectin A_{1a}, 4''-(acetylamino)-5-O-demethyl-4''-deoxy-, (4''R)-;

(2aE,4E,5'S,6S,6'R,7S,8E,11R,13S,15S,17aR,20R,20aR,20bS)-6'--(S)-sec-butyl-5',6,6',7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5',6,8,19-tetramethyl-17-oxospiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2'-[2H]pyran]-7-yl-4-O-(4-acetamido-2,4,6-trideoxy-3-O-methyl-α-L-lyxo-hexopyranosyl)-2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranoside [or (4''R)-4''-(acetylamino)-5-O-demethyl-4''-deoxyavermectin A_{1a}] CAS RN®: 133305-88-1; UNII: 00OY54D31C.

Component B_{1b}Avermectin A_{1a}, 4''-(acetylamino)-5-O-demethyl-25-de(1-methylpropyl)-4''-deoxy-25-(1-methylethyl)-, (4''R)-;

(2aE,4E,5'S,6S,6'R,7S,8E,11R,13S,15S,17aR,20R,20aR,20bS)-5',6,6',7,10,11,14,15,17a,20,20a,20b-Dodecahydro-20,20b-dihydroxy-6'-isopropyl-5',6,8,19-tetramethyl-17-oxospiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2'-[2H]pyran]-7-yl-4-O-(4-acetamido-2,4,6-trideoxy-3-O-methyl-α-L-lyxo-hexopyranosyl)-2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranoside [or (4''R)-4''-(acetylamino)-5-O-demethyl-25-de(1-methyl-propyl)-4''-deoxy-25-(1-methylethyl)avermectin A_{1a}] CAS RN®: 133305-89-2; UNII: 31OML2QZ0Q.

DEFINITION

Eprinomectin is a mixture of component B_{1a} ($C_{50}H_{75}NO_{14}$) and component B_{1b} ($C_{49}H_{73}NO_{14}$). It contains NLT 90.0% of component B_{1a} ($C_{50}H_{75}NO_{14}$) and NLT 95.0% of components B_{1a} ($C_{50}H_{75}NO_{14}$) and B_{1b} ($C_{49}H_{73}NO_{14}$), calculated on the anhydrous, solvent-free, and antioxidant-free basis. It may contain small amounts of a suitable antioxidant.

IDENTIFICATION

Change to read:

- A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-MAY-2020)
- B.** The retention times of the component B_{1a} peak and the component B_{1b} peak of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: 0.1% (v/v) solution of [perchloric acid](#) in [water](#)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	45	



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Time (min)	Solution A (%)	Solution B (%)
15	45	55
25	5	95
30	45	55
35	45	55

Diluent: [Methanol](#) and [water](#) (4:1)

Standard solution: 0.500 mg/mL of [USP Eprinomectin RS](#) in *Diluent*

System suitability solution: Transfer 4 mL of *Standard solution* to an LC vial. Add 2 drops of 1 M [sodium hydroxide](#) and let stand for 20 min prior to injection.

Sample solution: 0.500 mg/mL of Eprinomectin in *Diluent*

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

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 15 μL

System suitability

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

[NOTE—For relative retention times, see [Table 2.](#)]

Table 2

Components of the System Suitability Solution	Relative Retention Time
Impurity A	0.55
Component B _{1b}	0.77
Component B _{1a}	1.00
Impurities C + D	1.05
Impurity E	1.28

Suitability requirements

Resolution: NLT 3 between component B_{1b} and component B_{1a}; NLT 1 between component B_{1a} and impurities C + D, *System suitability solution*

Column efficiency: NLT 4,500 theoretical plates for component B_{1a}, *System suitability solution*

Symmetry factor: NMT 1.5 for component B_{1a}, *System suitability solution*

Relative standard deviation: NMT 1.0% from five injections for component B_{1a}, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of component B_{1a} (C₅₀H₇₅NO₁₄) in the portion of Eprinomectin taken:

Result = $[r_{1a}/(r_{1a} + r_{1b})] \times 100$

r_{1a} = peak area of component B_{1a} from the *Sample solution*

r_{1b} = peak area of component B_{1b} from the *Sample solution*

Calculate the percentage of component B_{1a} (C₅₀H₇₅NO₁₄) and component B_{1b} (C₄₉H₇₃NO₁₄) in the portion of Eprinomectin taken:

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