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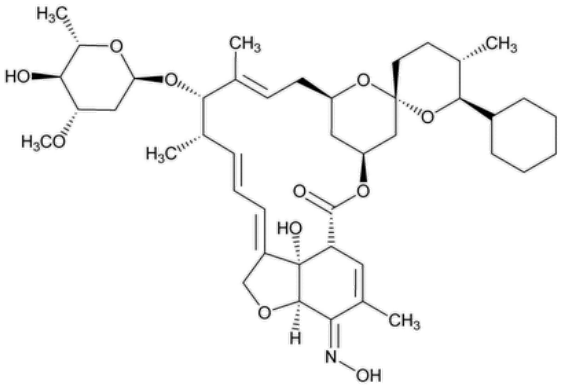
Selamectin



$C_{43}H_{63}NO_{11}$ 769.96

25-Cyclohexyl-4'-*O*-de(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-(hydroxyimino)-avermectin A1a;

(2a*E*,4*E*,5'*S*,6*S*,6'*S*,7*S*,8*E*,11*R*,13*R*,15*S*,17a*R*,20a*R*,20b*S*)-6'-Cyclohexyl-7-[(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)oxy]-3',4',5',6,6',7,10,11,14,15,20a,20b-dodecahydro-20b-hydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2'-[2*H*]pyran]-17,20(17a*H*)-dione 20-oxime CAS RN®: 220119-17-5.

DEFINITION

Selamectin contains NLT 96.0% and NMT 102.0% of selamectin ($C_{43}H_{63}NO_{11}$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A, 197K, or 197M▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (80:20)

Standard solution: 0.2 mg/mL of USP Selamectin RS in *Mobile phase*

Sample solution: 0.2 mg/mL of Selamectin in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 243 nm

Column: 3.9-mm × 15-cm; 4-µm packing L1

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of selamectin ($C_{43}H_{63}NO_{11}$) in the portion of Selamectin taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 96.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

- **Residue on Ignition ⟨281⟩**

Sample: 1.0 g

Acceptance criteria: NMT 0.1%

- **Organic Impurities**

Solution A: Water

Solution B: Acetonitrile

Mobile phase: See *Table 1*. Return to original conditions and re-equilibrate the system.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	40	60
28	40	60
45	20	80

Diluent: Acetonitrile and water (60:40)

Standard solution: 2.5 µg/mL of USP Selamectin RS in *Diluent*

Sample solution: 500 µg/mL of Selamectin in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 243 nm

Column: 3.9-mm × 15-cm; 4-µm packing L1

Column temperature: 30°

Flow rate: 2.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.6 for the selamectin peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Selamectin taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

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

C_S = concentration of USP Selamectin RS in the *Standard solution* (µg/mL)

C_U = concentration of Selamectin in the *Sample solution* (µg/mL)

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*. The reporting threshold for impurities is 0.2%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Hydroxyselamectin[a]	0.2	1.0	2.0
Didehydroselamectin[b]	0.4	1.0	2.0
Selamectin aglycone[c]	0.5	1.2	1.5
Selamectin	1.0	—	—
α-Oleandrosyl selamectin[d]	1.7	0.67	1.5
Any other individual impurity	—	1.0	1.0
Total impurities	—	—	4.0

[a] (2a*E*,2'*R*,4*E*,5'*S*,6*S*,6'*S*,7*S*,8*E*,11*R*,13*R*,15*S*,17a*R*,20a*R*,20b*S*)-6'-Cyclohexyl-7-[(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)oxy]-3',4',5',6,6',7,10,11,14,15,20a,20b-dodecahydro-4',20b-dihydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2'-[2*H*]pyran]-17,20(17a*H*)-dione 20-oxime.

[b] (2a*E*,4*E*,5'*S*,6*S*,6'*S*,7*S*,8*E*,11*R*,13*S*,15*S*,17a*R*,20a*R*,20b*S*)-6'-Cyclohexyl-7-[(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)oxy]-5',6,6',7,10,11,14,15,20a,20b-decahydro-20b-hydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2'-[2*H*]pyran]-17,20(17a*H*)-dione 20-oxime.

[c] (2a*E*,4*E*,5'*S*,6*S*,6'*S*,7*S*,8*E*,11*R*,13*S*,15*S*,17a*R*,20a*R*,20b*S*)-6'-Cyclohexyl-5',6,6',7,10,11,14,15,20a,20b-decahydro-7,20b-dihydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2'-[2*H*]pyran]-17,20(17a*H*)-dione 20-oxime.

[d] (2a*E*,4*E*,5'*S*,6*S*,6'*S*,7*S*,8*E*,11*R*,13*R*,15*S*,17a*R*,20a*R*,20b*S*)-6'-Cyclohexyl-7-[(4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)oxy]-3',4',5',6,6',7,10,11,14,15,20a,20b-dodecahydro-20b-hydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2'-[2*H*]pyran]-17,20(17a*H*)-dione 20-oxime.

SPECIFIC TESTS

- **WATER DETERMINATION ⟨921⟩, *Method I, Method Ia***

  Sample: 0.20 g

  Acceptance criteria: NMT 7.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in a tight container.
- **LABELING:** Label it to indicate that it is for veterinary use only.
- **USP REFERENCE STANDARDS ⟨11⟩**

  USP Selamectin RS

Topic/Question	Contact	Expert Committee
SELAMECTIN	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

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