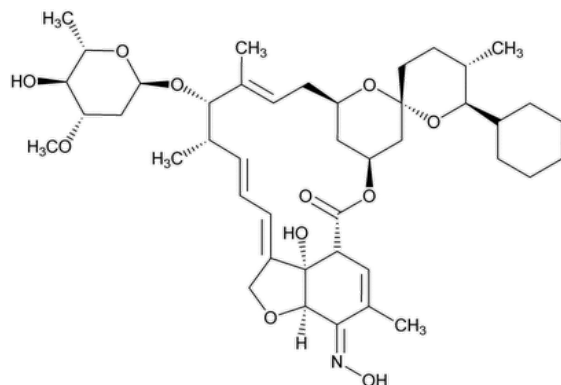


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Selamectin



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

(2aE,4E,5'S,6S,6'S,7S,8E,11R,13R,15S,17aR,20aR,20bS)-6'-Cyclohexyl-7-[(2,6-dideoxy-3-O-methyl- α -L-arabino-hexopyranosyl)oxy]-3',4',5',6',7,10,11,14,15,20a,20b-dodecahydro-20b-hydroxy-5',6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2'-[2H]pyran]-17,20(17aH)-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- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 20 μ L

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*