# Selamectin

**Published on:** 19 December, 2022 **Last date for comments:** 27 January, 2023

This draft proposal contains monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

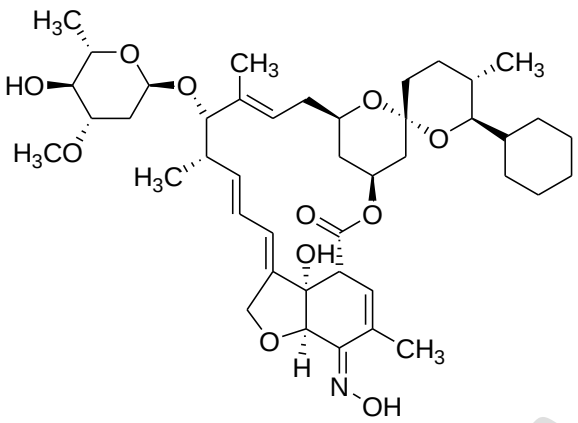
**Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.**

Draft for Comments

## Document History and Schedule for the Adoption Process

| Description | Details |
|---|---|
| Document version | 2.0 |
| Monograph proposed for inclusion | IP Addendum 2024 |
| Tentative effective date of monograph | April, 2024 |
| First draft published on IPC website for public comments | 26 August, 2022 |
| Draft revision published on IPC website for public comments | 19 December, 2022 (version 2.0) |
| Further follow-up action as required. | |

# Selamectin



$C_{43}H_{63}NO_{11}$ Mol. Wt. 770.0

Selamectin is 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;

Selamectin contains not less than 96.0 per cent and not more than 102.0 per cent of $C_{43}H_{63}NO_{11}$, calculated on the anhydrous and solvent-free basis.

**Category**. Anti-parasitic.

**Description**. A white to yellowish white powder.

## Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *selamectin IPRS* or with the reference spectrum of Selamectin.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

## Tests

**Related substances**. Determine by liquid chromatography (2.4.14).

*Solvent mixture.* 60 volumes of *acetonitrile* and 40 volumes of *water*.

*Test solution*. Dissolve 50 mg of the substance under examination in the solvent mixture and dilute to 100.0 ml with the solvent mixture.

*Reference solution.* A 0.025 per cent w/v solution of *selamectin IPRS* in the solvent mixture. Dilute 1.0 ml the solution to 100.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm × 3.9 mm, packed with octadecylsilane bonded to porous silica (4 µm) (Such as Nova-Pak C18),
- mobile phase: A. *water*,
  B. *acetonitrile*,
- flow rate: 2 ml per minute,
- a gradient programme using the conditions given below,

DRAFT FOR COMMENTS

– spectrophotometer set at 243 nm,
– injection volume: 20 µl.

| Time (in min.) | Mobile phase A (per cent v/v) | Mobile phase B (per cent v/v) |
|---|---|---|
| 0 | 40 | 60 |
| 28 | 40 | 60 |
| 45 | 20 | 80 |
| 45.1 | 40 | 60 |
| 50 | 40 | 60 |

| Name | Relative retention time | Correction factor |
|---|---|---|
| Hydroxyselamectin[1] | 0.2 | -- |
| Didehydroselamectin[2] | 0.4 | -- |
| Selamectin aglycone[3] | 0.5 | 0.83 |
| Selamectin | 1.0 | -- |
| α-Oleandrosyl selamectin[4] | 1.7 | 1.49 |

[1](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.

[2](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.

[3](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.

[4](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*)-dione20-oxime.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 1.6.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to hydroxyselamectin and didehydroselamectin, each of, is not more than 4 times the area of the principal peak in the chromatogram obtained with the reference solution (2.0 per cent), the area of any peak corresponding to selamectin aglycone and α-oleandrosyl selamectin, each of, is not more than 3 times the area of the principal peak in the chromatogram obtained with the reference solution (1.5 per cent), the area of any other secondary peak is not more than twice the area of the principal peak in the chromatogram obtained with the reference solution (1.0 per cent) and the sum of the areas of all the secondary peaks is not more than 8 times the area of the principal peak in the chromatogram with the reference solution (4.0 per cent). Ignore any peak with an area less than 0.4 times the area of the principal peak in the chromatogram obtained with the reference solution (0.2 per cent).

**Heavy metals** (2.3.13). 1.0 g complies with limit test for heavy metals, Method B (20 ppm).

**Sulphated ash** (2.3.18). Not more than 0.1 per cent.

**Water** (2.3.43). Not more than 7.0 per cent, determined on 0.2g.

**Assay.** Determine by liquid chromatography (2.4.14),

*Test solution*. Dissolve 20 mg of the substance under examination in the mobile phase and dilute to 100.0 ml with the mobile phase.

*Reference solution.* A 0.02 per cent w/v solution of *selamectin IPRS* in the mobile phase.

Chromatographic system
– a stainless steel column 15 cm × 3.9 mm, packed with octadecylsilane bonded to porous silica (4 µm)
– mobile phase: a mixture of 80 volumes of *acetonitrile* and 20 volumes of *water*.
– flow rate: 1 ml per minute,
– spectrophotometer set at 243 nm,
– injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 1.0 per cent.

DRAFT FOR COMMENTS

Inject the reference solution and the test solution.

Calculate the content of $C_{43}H_{63}NO_{11}$.

**Storage**. Store protected from moisture, at a temperature not exceeding 30°.

DRAFT FOR COMMENTS