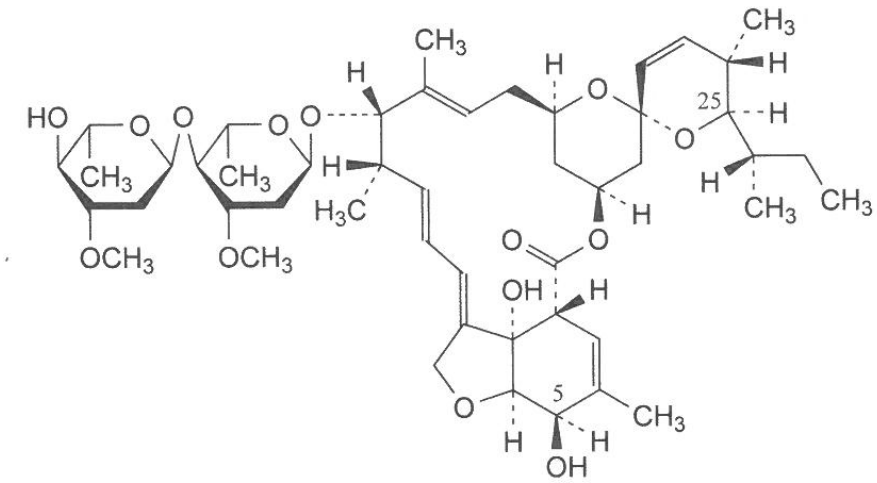
2.1.P.5.5 Characterisation of Impurities

1 Potential organic impurities of Ivermectin 3 mg tablet as listed in the European Pharmacopoeia:

Impurity A (Avermectin B_{1a})

Chemical name: 5-O-demethylavermectin A_{1a}

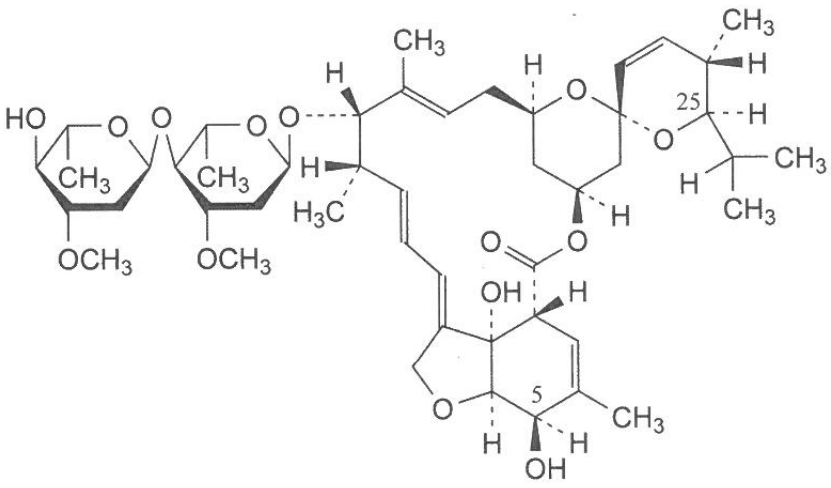
Structural formula:



Impurity B (Avermectin B_{1a})

Chemical name: 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methyl-ethyl)avermectin A_{1a}

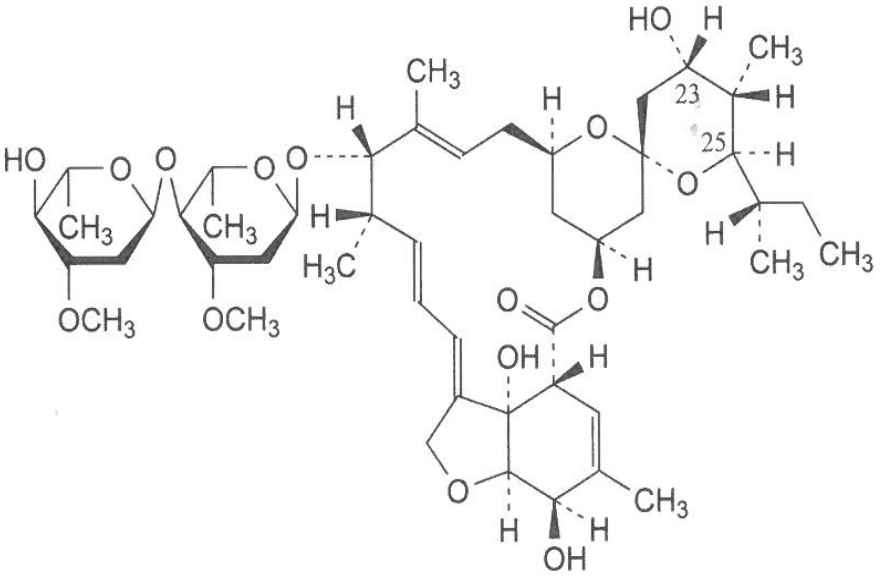
Structural formula:



Impurity C (Avermectin B_{2a})

Chemical name: *(23S)*5-O-demethyl-23-hydroxy-22,23-dihydroxy avermectin A_{1a}

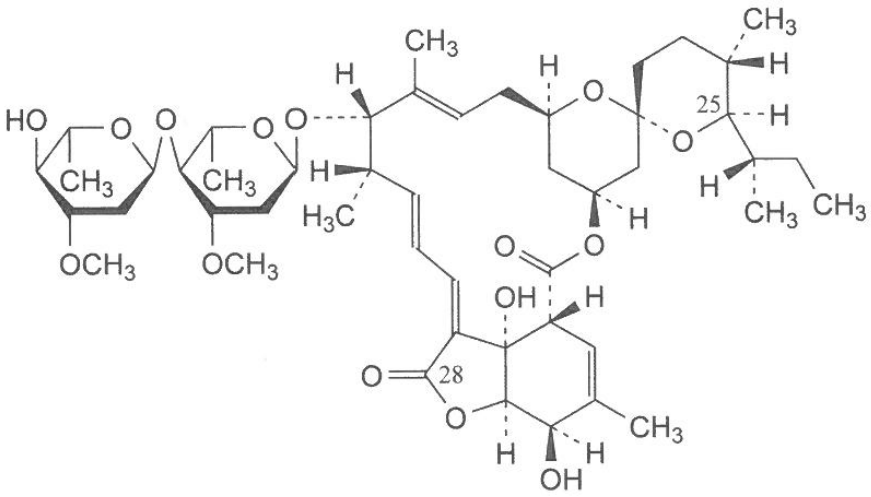
Structural formula:



Impurity D (28-oxoH_2B_{1b})

Chemical name: 5-O-demethyl-28-oxo-22,23-dihydroxy avermectin A_{1a}

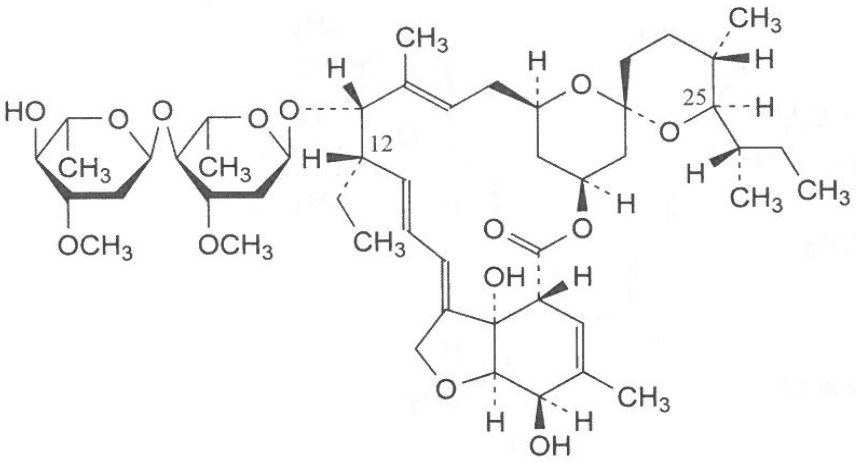
Structural formula:



Impurity E (12-demethyl-12-ethyl-H_2B_{1a})

Chemical name: 5-O,12-didemethyl-12-ethyl-22,23-dihydroavermectin A_{1a}

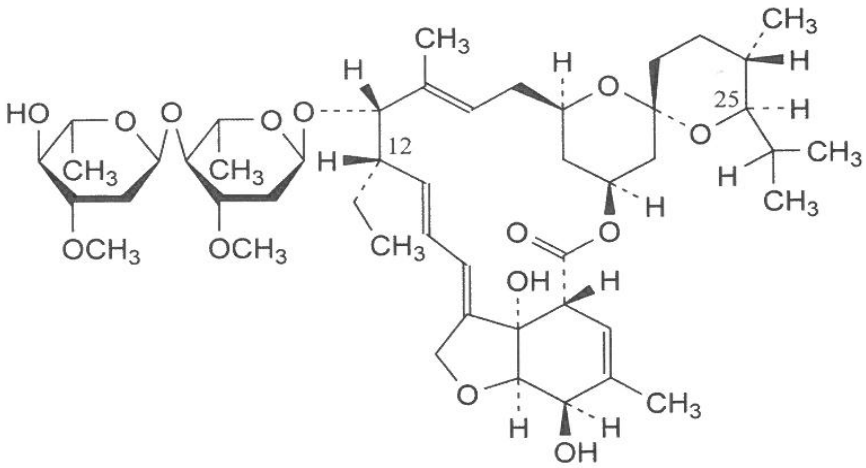
Structural formula:



Impurity F (12-demethyl-12-ethyl-H_2B_{1b})

Chemical name: 5-O,12-didemethyl-25-de(1-methylpropyl)-12-ethyl-25-(1-methylethyl)-22,23-dihydroavermectin A_{1a}

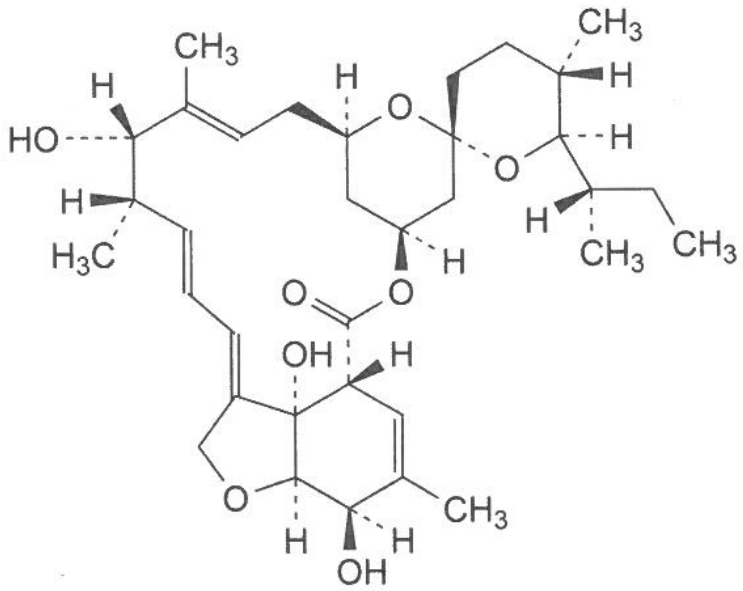
Structural formula:



Impurity G (H_2B_{1a} aglycone)

Chemical name: *(6R,13S,25R)*5-O-didemethyl-28-deoxy-6,28-epoxy-13-hydroxy-25-[(1S)-1-methylpropyl]milbemycin B

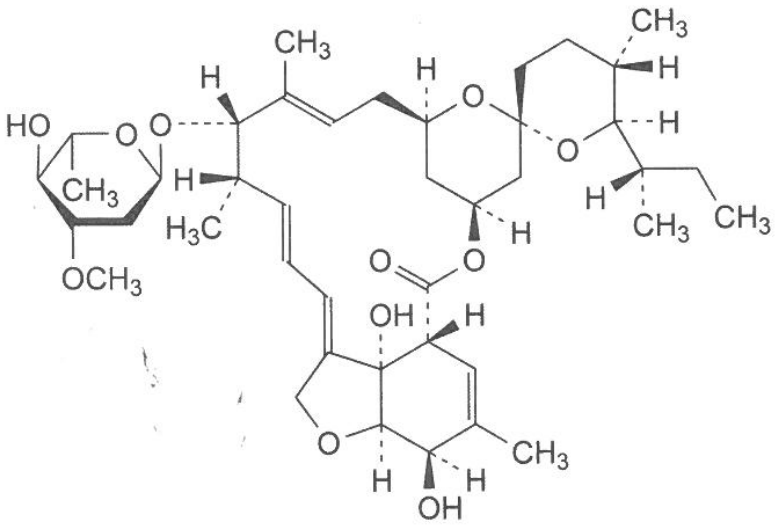
Structural formula:



Impurity H

Chemical name: 4'-O-de(2,6-didedoxy-3-O-methyl-α-L-*arabino*-hexo-pyranosyl)-5-O-demethyl-22,23-dihydroavermectin A_{1a}

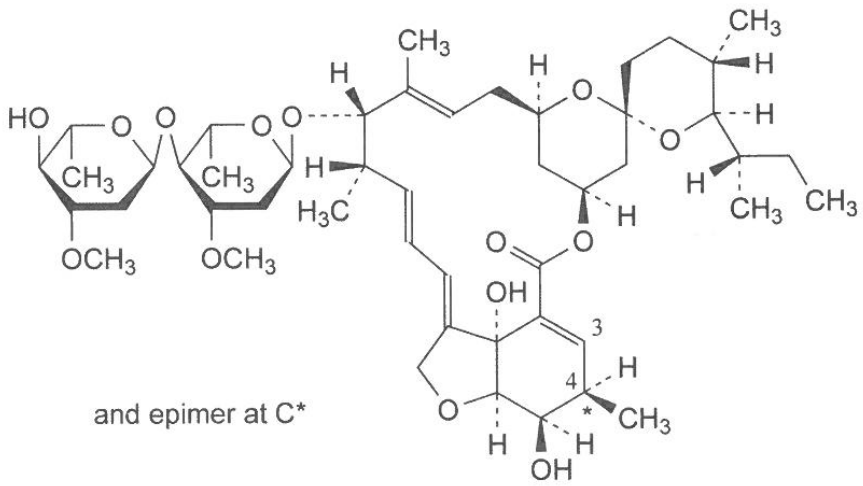
Structural formula:



Impurity I ($\Delta^{2,3}H_2B_{1a}$)

Chemical name: 2,3-didehydro-5-O-demethyl-3,4,22,23-tetrahydroavermectin A_{1a}

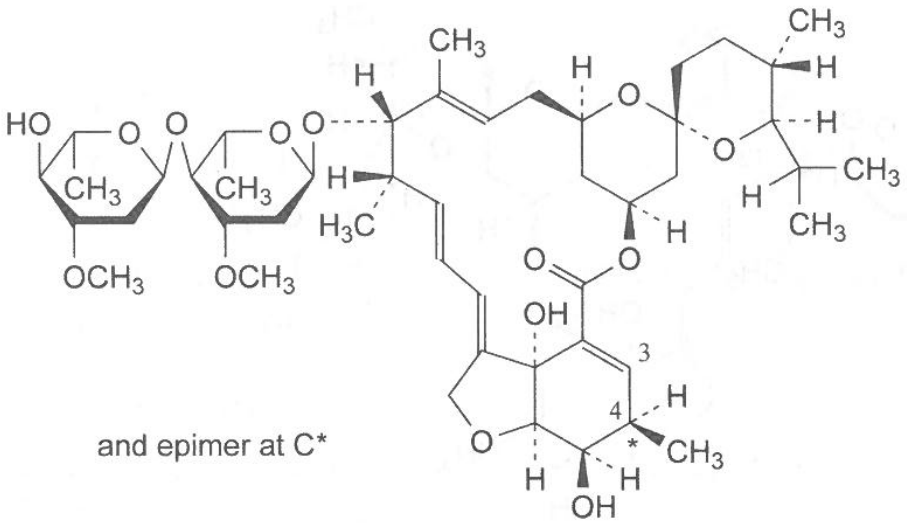
Structural formula:



Impurity J($\Delta^{2,3}H_2B_{1b}$)

Chemical name: 2,3-didehydro-5-O-demethyl-25-de(1-methylpropyl)- 25-(1-methylethyl)-3,4,22,23-tetrahydroavermectin A_{1a}

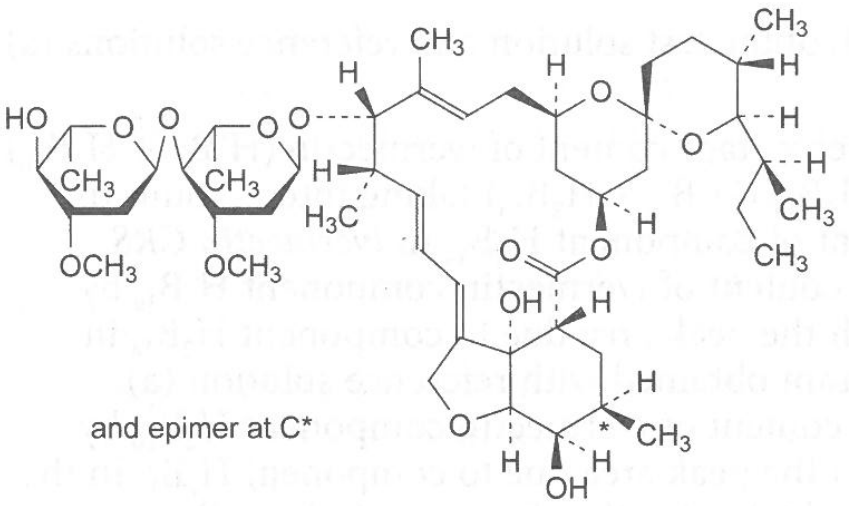
Structural formula:



Impurity K (H_4B_{1a} isomer)

Chemical name: *(4R) and (4S)*-5-O-demethyl-3,4,22,23-tetrahydroavermectin A_{1a}

Structural formula:



Residual solvents

No residual solvents used during manufacturing. The potential residual solvents analysed and controlled during API testing.

Inorganic impurities

Inorganic impurities are analysed and controlled during the testing of the API and the excipients.

Genotoxic impurities

No information available about the potential genotoxic impurities.