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Avermectin, the Nobel Prize Winner Drug in Cyclodextrin-Enabled Formulations

The 2015 Nobel prize in Physiology and Medicine was shared by Y. Tu for the discovery of the antimalarial artemisinin (see the 2016 March issue of the Cyclodextrin News) and William C. Campbell and Satoshi Ōmura who discovered avermectin, the derivatives of which have radically lowered the incidence of River Blindness and Lymphatic Filariasis, as well as showing efficacy against an expanding number of other parasitic diseases. [1] It was Ōmura of Kitasato University (Tokyo) who identified avermectin from the bacterium *Streptomyces avermitilis* and Campbell of the Merck Institute for Therapeutic Research who purified avermectin from the cultures and discovered ivermectin, a derivative of greater potency and lower toxicity. [2]

Onchocerciasis, also known as River Blindness, is a disease caused by infection with the parasitic worm *Onchocerca volvulus*. The parasite worm is spread by the bites of black fly (Figure 1). These flies live near to rivers in sub-Saharan Africa, hence the name of the disease. There is no vaccine against it. Insecticides are used to decrease the fly population. People infected are treated with ivermectin. The drug kills the larvae but not the adult worm therefore the treatment should be repeated once or twice a year. Ivermectin donated by Merck has been used in 33 countries in sub-Saharan Africa, Latin America and Yemen, where River Blindness is endemic. [3]

Lymphatic Filariasis known also as elephanthiasis because of abnormal enlargement of body parts is caused by parasitic worms of the family Filariodidea. [4] *Wuchereria bancrofti* is responsible for 90% of the infections. Infection occurs when filiarial parasites are transmitted to humans by mosquitoes (Figure 1). The preventive treatment involves combined therapy with albendazole and ivermectin. More than a billion people have been treated in the frame of the preventive chemotherapy of WHO's Global Program to Eliminate Lymphatic Filariasis in 63 countries. [4,5]

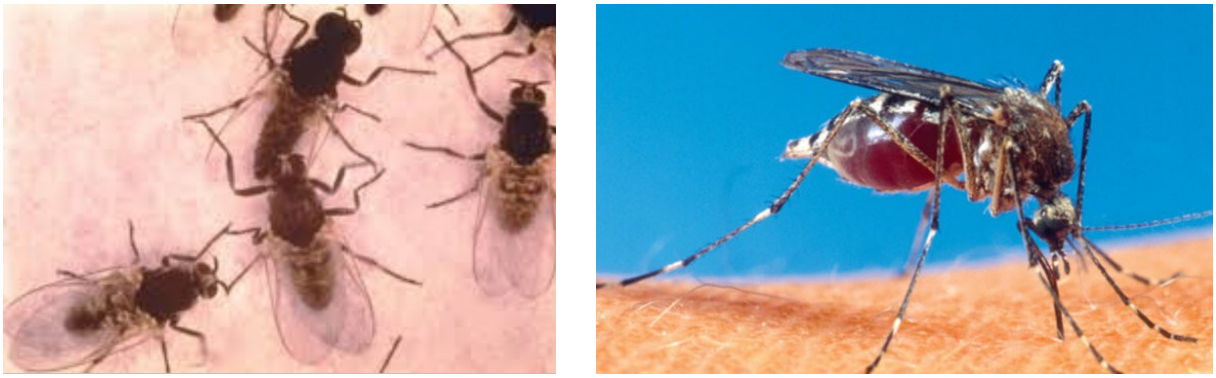

Fig. 1 Transmitters of the infection

Although avermectins have been discovered for decades, their potential has been only recently recognized. Avermectins are a series of macrocyclic lactone derivatives with antiparasitic effect. Ivermectin is a mixture containing at least 90% 5-O-demethyl-22,23-dihydroavermectin A_{1a} and less than 10% 5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)avermectin A_{1a} , generally referred to as 22,23-dihydroavermectin B_{1a} and B_{1b} , or H_2B_{1a} and H_2B_{1b}, respectively (Figure 2). It is insoluble in water but soluble in methanol and 95% ethanol. [5] It is sensitive to light and oxygen as well as to hydrolysis. CD-based formulations aimed at improving the solubility and stability have been developed. It is easy to understand the importance of novel formulations as ivermectin is not compatible with numerous commonly used excipients [6].

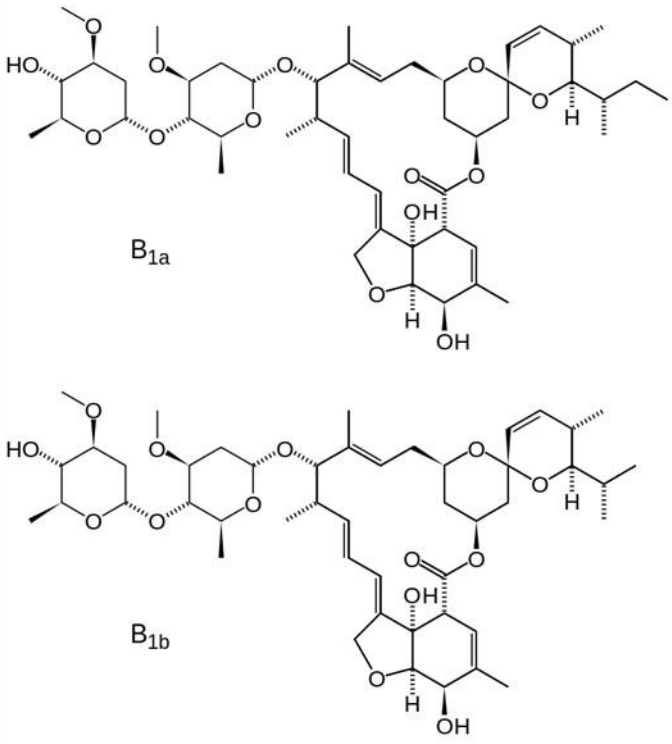

Fig. 2 Chemical structure of avermectins

Ivermectin formulation of enhanced solubility was obtained by preparing its CD complex. [7] The photostability of abamectin (containing more than 80% avermectin B1a and less than 20% avermectin 1Bb) was improved by complexation. [8] IR studies proved that intermolecular H-bond was formed between abamectin and BCD.

Various veterinary drugs including ivermectin, and avermectin, were solubilized by BCD derivatives such as carboxymethyl-, hydroxypropyl-, and sulfobutyl-BCD [9] or hydroxypropyl-, glucosyl-, 2,6-dimethyl-, hydroxyethyl-, or maltosyl-BCD [10]. The complexes were prepared by freeze drying or milling or by ultrasonic suspension method.

Water soluble ivermectin solubilized by RAMEB has been marketed. [11]

Methylamino avermectin benzoate was complexed with BCD. [12] Slow release avermectin formulation was developed by using CD and emulsifier (Tween-80), which shows retarded heat degradation and reduced hydrolysis. [13]

Wettable ivermectin solid dispersion powder was obtained by complexing with HPBCD. [14] The formulation contained also antioxidants. An optimum process for including ivermectin into HPBCD was investigated by an orthogonal design for the development of new formulations of ivermectin. [15]

All the three parent CDs, their hydroxypropyl and methyl derivatives were published in another patent. [16] The pharmaceutical composition disclosed was a combination with mylbemycin to be added to the food of domestic animals to treat helminthiasis (worm infection). Another combination with praziquantel is prepared as anthelmintic paste in the form of an aqueous suspension. It comprises a macrocyclic lactone selected from avermectins, milbemycins and their derivatives, a CD, a thickener, and water. The suspension formulations of the invention are useful for controlling endoparasites in warm-blooded animals. [17] A third combination medicine contains griseofulvin and abamectin or ivermectin formulated with BCD useful for preventing and treating ringworm and mite of rabbit, pig, sheep, dog, cat and cattle. [18]

Emulsion is prepared by mixing avermectin with BCD or GCD and cosolvent with emulsifying agent fatty alcohol polyoxyethylene ether, sorbitan monooleate and polyoxyethylene sorbitan monolaurate. The emulsion showed sustained-release and improved solubility. It solved also the problems of instability of avermectin against the effect of light, oxygen, heat, acid, alkali, etc. [19] A water-based microemulsion containing avermectin among others can be used for killing and controlling insects, mites and mold in plants and storage of food, tobacco, herbs, leather, clothing, books, etc. and reduce the loss of stored product, food and plant caused by pests and mold. [20]

In situ forming gels for ophthalmic applications is used to deliver antiparasitics and/or antiprotozoals (ivermectin, pyrimethamine, trisulfapidimidine, clindamycin, corticosteroids), among others. As film forming carbohydrates cyclodextrins and their polymers are also mentioned. Compositions can be optimized for physiological tolerance in the eye by formulating to have hyperosmotic, hypo-osmotic or iso-osmotic characteristics in the gel state and have increased resistance to shear thinning. No burning or other discomfort feeling was observed upon application to the eye. Gels are retained at the desired locus for longer intervals increasing the efficiency of action of the delivered drug. [21]

Microparticles were obtained by combining ivermectin/CD complex with bletilla striata gels. By using these microparticles mixed to the food the inconvenience of the injection can be avoided, lower loss on hydrolysis can be observed. [22]

Nanoparticles for controlled release of avermectin were prepared using BCD as a carrier by a co-precipitation method. The controlled release properties of the nanoparticles were clearly demonstrated: 98.04% of avermectin was released from a dialysis bag containing free avermectin after 18 h, whereas after 96 h, only 94.20% of avermectin was released from a dialysis bag containing the nanoparticles. The UV-shielding properties of the nanoparticles have been also proved. [23]

Microencapsulated pesticidal fertilizer was disclosed by mixing the pesticide microcapsule with organic fertilizer. The pesticide was selected from nicotine, avermectin and/or pyrethrin. The microencapsulated pesticidal fertilizer may be used as both pesticide and fertilizer, with the advantages of masking and sustained releasing effects, good chemical compatibility, good physical stability, low cost, long action and simple preparation process. [24]

Recently, novel applications have been discovered: Intraperitoneal injection of CD-conjugated ivermectin proved to be effective in inhibition of transcription factor (TCF)-dependent human colon cancer xenograft *in vivo*. [25]

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Bone diseases, Amino- and histidinyl-modified amphiphilic β-cyclodextrins, Osteoclast inhibitor, Emulsion solvent evaporation technique, Cytotoxicity

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Food spoilage, Antimicrobal and antioxidant activities, Complexation efficiency, Molecular modeling

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β-Cyclodextrin, Bioconversion of cholesterol by cholesterol oxidase, Consumer acceptability parameters, Chitosan

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Brown rice flour, β-Cyclodextrin, Response surface methodology, Ar-turmerone, 2-Methyl-4-vinylguaiacol, Marker compounds

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Drug delivery, Cell and gene therapy, Tissue engineering, Protein patterning, Host polymer, Guest polymer, Photo-, pH- and thermo-sensitivity, Cytocompatibility

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Chelating agent, Succinyl-β-cyclodextrin, 3-Aminopropyl triethoxsilane

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Low-cost adsorbent, Freundlich isotherm

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Direct electron transfer, Pyrene/β-cyclodextrin host guest interactions, β-Cyclodextrin-modified gold nanoparticles

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Methylated cyclodextrins, Methyl jasmonate, Metabolic engineering-based strategy

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Porous metal-organic frameworks, γ-CD, Alkali metal salts, Separation of mixtures of alkylaromatic compounds, BTEX mixture, Structural isomers of pinene and terpinine, Mono- and disubstituted haloaromatic compounds, HPLC stationary phase

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Hydrogels, Adsorption of cationic methylene blue, Electrochemical responses toward dopamine, tyrosine and uric acid

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Enzyme-free nucleic acid-based signal amplification, Biosensors, Adenosine-aptamer, Human serum samples

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Chloramphenicol, Thymine, Amperometric detection

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Pyrene functionalized initiator, Nonmetalloproteins, Metalloproteins, Tunable selectivity and sensitivity

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