CYCLODEXTRIN NEWS

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Cyclodextrin microparticles for ocular drug delivery targeted to the posterior segment of the eye

The conventional ophthalmic drug delivery systems cannot ensure the required concentration of the drug due to the short contact time of the formulations on the epithelium and fast elimination of drugs. To overcome these problems various concepts such as prodrugs, solubilizers (cyclodextrins), penetration enhancers and other ocular drug delivery systems such as gels, in-situ forming gels with temperature-, pH-, or osmotically induced gelation, combination of polymers and colloidal systems such as liposomes, microemulsions, nanoemulsions, niosomes, cubosomes and nanoparticles have been studied (Achuri et al., 2013).

According to the Cyclodextrin News database containing over 300 entries on ophthalmic application of cyclodextrins, the development of cyclodextrin-containing ophthalmic formulations started in the eighties with solubilization/stabilization of steroids and non-steroidal antiinflammatory drugs. In certain studies the complexation resulted in slightly improved bioavailability and reduced irritancy. Based on the three decades of research and development there are at least 5 CD-enabled eye drop formulations on the market (Table 1).

Table 1 CD-containing eye drops marketed

Drug	CD	Trade name	Company
Chloramphenicol	RAMEB	Clorocil	Oftalder (Portugal)
Diclofenac	HPGCD	Voltaren/ Voltarol	Novartis (Schwitzerland)
Indomethacin	HPBCD	Indocid/Indocyllir	Chauvin (UK)/ Baush & Lomb (US)
Naphasoline hydrochloride	CD	Clear eyes Cooling comfort	Medtech (S. Africa)
Thimerosal	BCD	Vitaseptol	Novartis (Schwitzerland), Europhta (Monaco)

The recent review of Loftsson and Stefánsson (2017) gives an overview on the application of cyclodextrins in the anterior and posterior segment of the eye. From this review one can learn that drug permeation from the eye surface into the eye is usually of very low efficiency mainly because of several barriers. The first barrier is the mucus, a gel-like fluid layer consisting of water (90–98%) and glycoproteins called mucins (2-5%). Mucins form H-bonds with the surrounding water building an unstirred water layer (UWL) hardly permeable for lipophilic drugs.

The drug permeating from the surface into the eye via passive drug diffusion follows two main routes: 1) corneal route (mucus→cornea→aqueous humor→intraocular tissues) and 2) scleral route (conjuctiva→sclera→choroid→retina). (The segments of eye are illustrated in Fig. 1).
Cornea consists of hydrophilic and lipophilic epithelium layers which hamper the penetration of lipophilic and hydrophilic drugs, respectively. Conjunctiva and sclera have also barrier function depending less on the hydrophilicity but rather on the size (molecular weight) of the drug: the permeability coefficient decreases with increasing hydrodynamic radius of the drug.
The passive transport of a drug depends also on the concentration gradient (the higher the better).
Another obstacle of the topical drug administration to the eye is the short residence time: the eye drop is mixed with tear (diluted resulting in decreased concentration then fast drying).
The higher drug concentration, the longer residence time and optimal lipophilicity (the octanol/water partition coefficient, Kow between 2 and 3) are favored for drug penetration into the eye.

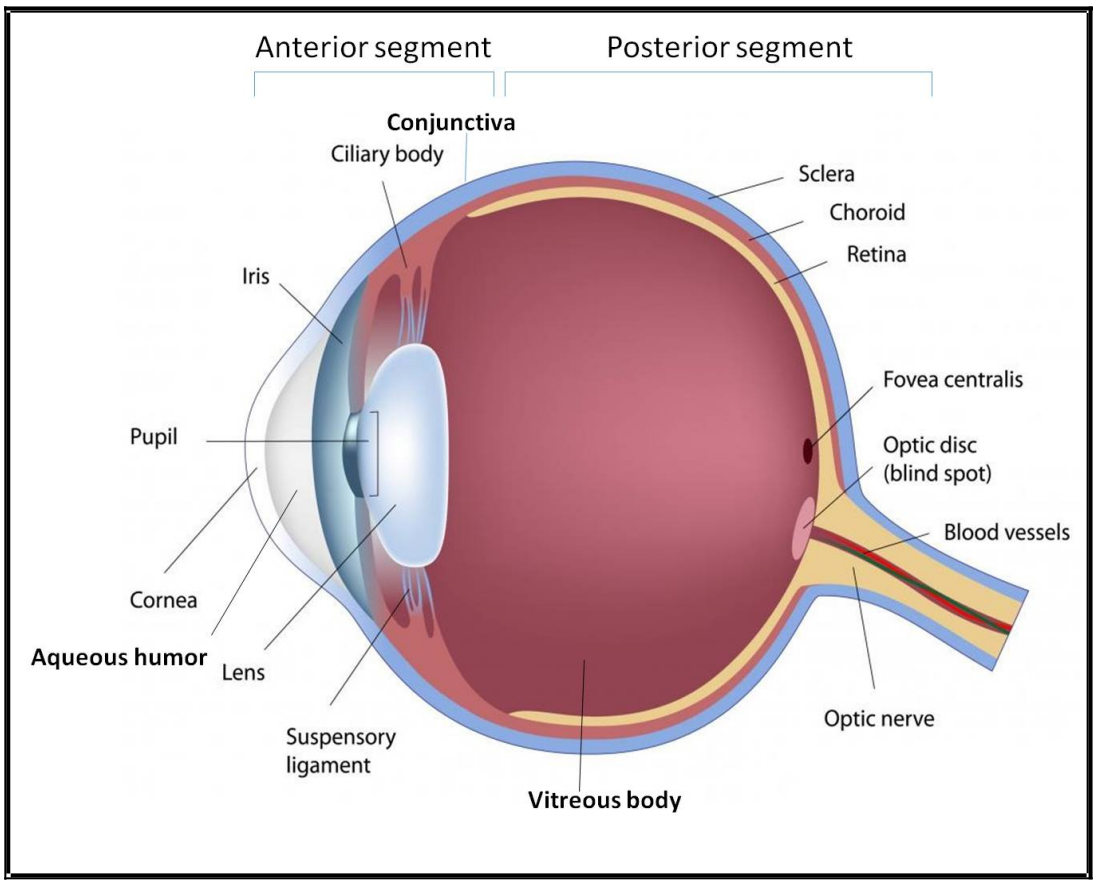

Fig. 1 The structure of the eye

It is especially difficult to obtain therapeutic drug concentrations in the posterior segment of the eye after topical application of aqueous, low viscosity eye drops.
The eye drops recently developed by Loftsson's group contain solid drug/cyclodextrin complex microparticles with a mean diameter of 2-4 μm, dissolved drug/cyclodextrin complex nanoparticles and dissolved drug molecules in equilibrium in an aqueous eye drop medium of low viscosity (Fig. 2).

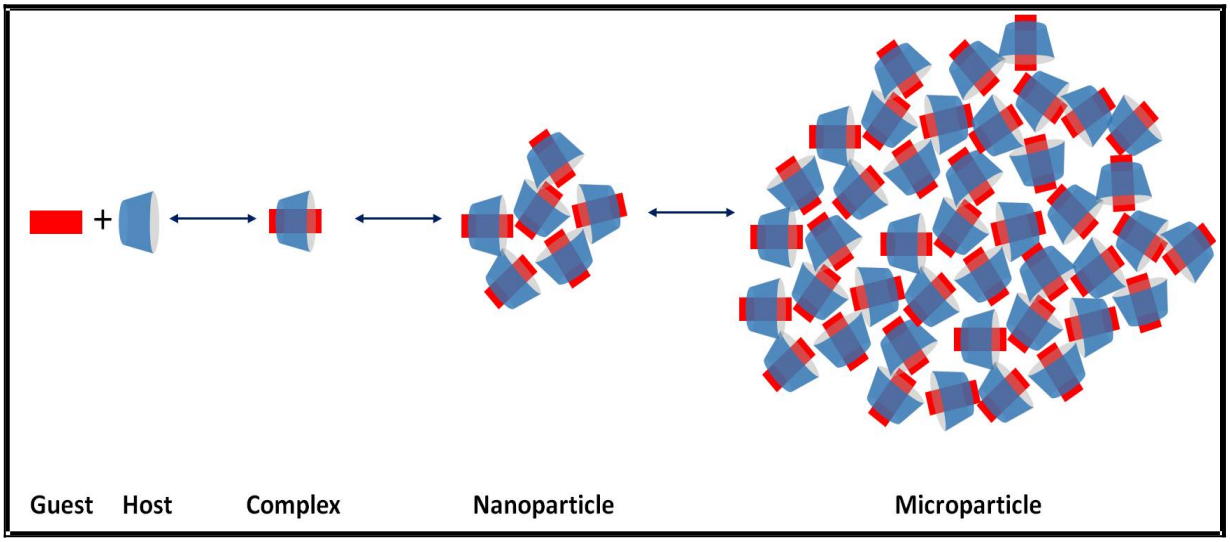

Fig. 2 In consequence of aggregation individual host and guest molecules are in equilibrium with inclusion complexes in non-aggregated form aggregated to nanoparticles (20–300 nm) and microparticles (1–10 μm) (redrawn from Loftsson and Stefansson, 2017)

After administration of the eye drops the microparticles slowly dissolve and maintain close to saturated drug concentrations in the aqueous tear fluid for several hours. Studies in rabbits using dexamethasone as sample drug, show that the eye drops deliver significant amounts of drugs to both the posterior segment and anterior segment of the eye while the clear solutions with RAMEB deliver the drug mainly to the anterior segment (Fig. 3).

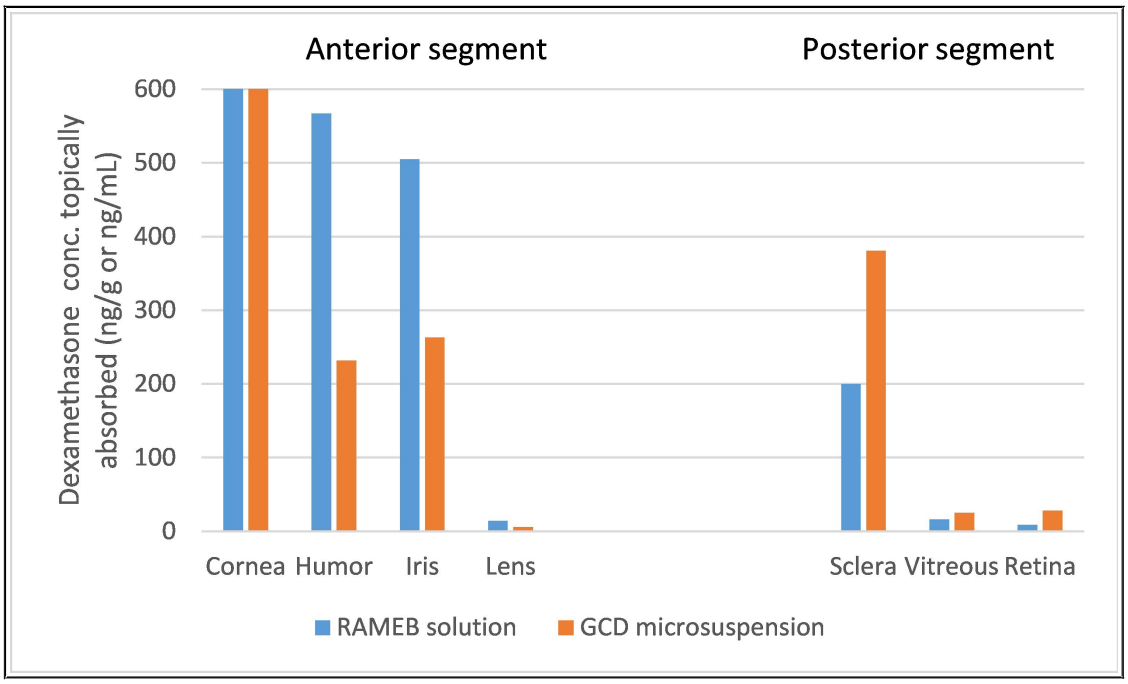

Fig. 3 Dexamethasone concentration 120 min after topical administration to rabbit in the various segments of the eye after using 1.5% Dexamethasone formulated by RAMEB solution and by GCD microsuspension (drawn from the data in Loftsson and Stefansson, 2017)

Clinical studies indicate that the eye drops can replace intravitreal injections and implants that are currently used to treat ophthalmic diseases, such as diabetic macular edema (DME), intermediate uveitis with cystoid macular edema, and decrease frequency of drug administration, both of which provide important benefits for the patients.

Based on this concept an EU supported consortium with the members of Oculis (Reykjavik), Experimentica Ltd. (US), Medical University of Vienna, Nucro-Technics (Toronto), University of Copenhagen and Zealand University Hospital (Copenhagen) started to develop a novel eye-drop formulation for the treatment of diabetic retinopathy.

Recently, Oculis closed a financing round of CHF 20 million for going to the clinical phases in the development of breakthrough non-invasive topical treatment for back-of-the-eye diseases (Oculis, 2018). The new technology using cyclodextrin-based microparticles is expected to pave way for the next generation of ophthalmic treatments.

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Cyclodextrin News Retrospective

We wrote 10, 20 and 30 years ago

10 years ago an updated list of approved and marketed pharmaceutical products containing cyclodextrins was the topic of the first issue of Vol 22. This collection was often cited in various publications. Followed by the exhaustive listing of various drug preparations, a cordial invitation was sent to the 14th International Cyclodextrin Symposium held in Kyoto, Japan (May 8-11, 2008). The international cyclodextrin community is certainly excited that after ten years the conference re-visits Japan and the 19th International Cyclodextrin Symposium will be organized in Tokyo (April 27-30, 2018).

20 years ago, the highlighted topic was „Cyclodextrins in pulmonary drug delivery systems".

Based on 25 publications known in 1998 related to the field, a short comprehensive outline was given on relevant questions and issues as listed below:

- Where does pulmonary drug absorption occur?
- What are the barriers for pulmonary absorption?
- What is the mechanism of pulmonary drug absorption?
- What variables affect pulmonary absorption?
- Dosing problems associated with pulmonary drug delivery.

In the resumé of Professor Szejtli a very apt short answer is given, literally: „**So CDs can help!**"
To the best of our knowledge no CD-containing pulmonary product has been successfully introduced to the market yet. However the state-of-the art approach to the potential future success lies in EMA's latest collective proposal related to the pharmaceutical use of CDs.

This document reflects to the possible pulmonary application: „Cyclodextrins are absorbed poorly via mucosal membranes, but at high doses they can increase nasal and pulmonary drug permeability by direct action on mucosal membranes and facilitate also their own absorption. They can also strongly potentiate lipophilic absorption enhancers. Less than 10% HP-β-CD or RM-β-CD solutions, and less than 1.5% β-CD solutions do not induce tissue damage in rats and can keep the integrity of the nasal mucosa" (Questions and answers on cyclodextrins used as excipients in medicinal products for human use: EMA/CHMP/495747/2013, 9 October 2017). The market potential of the field is exemplified by a granted patent entitled „Inhalant Formulation Containing Sulfoalkyl Ether Cyclodextrin And Corticosteroid" owned by CyDex Pharmaceuticals, Inc., USA under patent number EP1732512.

30 years ago, Professor Szejtli postulated that it is still possible to be addictive to the passion of smoking while a smart cigarette tip is capturing the harmful substances by cyclodextrin. In his editorial entitled „Safer smoking with cyclodextrins" the ability of cyclodextrins to complex nicotine and tar components is shown. The use of this property in a filtration system led to a marketed product in Japan (Disposable Cigarette Filter) depicted in Vol 2 issue 5 of Cyclodextrin News. Professor Szejtli's sense of humor reflected at the ending note of the editorial: „This product would seem to be an excellent idea to make smoking safer. As a non smoker, however, the logic of removing both tar and nicotine escapes me. What is left? Possibly the HCN!!"

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