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Cost effective preservatives free ophthalmic formulation

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***Abstract*---**The present invention is directed to a method for producing an ophthalmic pharmaceutical formulation containing a carbonic anhydrase inhibitor, hydroxyl ethyl cellulose (HEC), and a beta-adrenergic antagonist for the treatment of ocular hypertension and glaucoma that is free of benzalkonium chloride and other preservatives. The current production technique is a simpler, more cost-effective method of preparing pharmaceutical ophthalmic formulations in a single tank without the usage of extra sterile-filtered tanks. For individuals with newly diagnosed glaucoma, optical therapy is usually the initial line of treatment. Preservatives are essential in all multi-dose ophthalmic drugs to maintain an antibacterial environment in the container, thus eye care professionals must be aware of the effects of preservatives on the ocular surface.

***Keywords*---**ophthalmic, ocular surface disease (OSD), cost effective preservatives.

Introduction (add more examples of preservatives and side effects of same)

Dry eye disease (DED) affects a substantial number of people (estimated prevalence range: 5 to 35 percent) who visit general ophthalmology clinics on a daily basis [1]. The condition is often chronic, affects more women than males, and worsens with age [2]. The major therapy for symptomatic alleviation in patients with DED is long-term use of lubricating eye drops. Preservatives are now required in the composition of roughly 70% of lubricating eye drops sold worldwide in order for them to be stable and sterile [3,4]. Detergents, oxidizing, and ionic-buffered preservatives are the most common types of chemicals used to preserve ophthalmic formulations [5,6]. The most commonly used preservative in ophthalmic drops, benzalkonium chloride (BAK), disrupts the tear film, increases

tear evaporation and molarity, and damages ocular surface epithelial cells [7,8]. The likelihood for serious ocular surface disease (OSD) due to cumulative toxicity is directly connected to the duration of therapy, the kind and number of various drugs necessary for treatment, as well as the amount of drops per day required to achieve therapeutic efficacy [9,10]. We routinely apply lubricating eye drops preserved with ingredients that enhance toxicity to the cornea and conjunctiva in our attempt to relieve the signs and symptoms of DED and so improve the quality of life of patients suffering from this prevalent condition. Figure 1: show the Preservative Free Eye Drops

Figure 1: Preservative Free Eye Drops (fig. and title is not relevant, add more clear picture)

Background of the invention (Needs to focus on Preservative free eye drop)

Glaucoma is an ocular degenerative condition in which the intraocular pressure is too high to allow normal vision. As a result, injury to the optic nerve head may develop, resulting in irreversible vision loss. Glaucoma can lead to blindness if left untreated. The majority of ophthalmologists now feel that ocular hypertension, or elevated intraocular pressure without optic nerve head injury or typical glaucomatous visual field abnormalities, is just the first stage of glaucoma.

Method and Solution (Add 1 or 2 more methods)

The fact that HEC is commercially accessible in two molecular weight ranges, 1.0 and 1.3 million Dalton, with an approximate diameter of roughly 0.1 and 0.13 microns correspondingly (assuming spherical shape) is one of the major issues with ocular formulations including HEC. HEC cannot be filtered by a sterilizing filter with a pore size of 0.22 microns since its diameter is so near to the filter's pore size. In yet another embodiment, the present invention pertains to a method of producing a pharmaceutical formulation for the treatment of ocular hypertension and glaucoma that is free of benzalkonium chloride and other preservatives. In another embodiment, the said ophthalmic pharmaceutical formulation will be superior in terms of safety and tolerability while preserving and/or improving its efficacy in the treatment of ocular hypertension and glaucoma. In another form, the invention pertains to the fabrication of ophthalmic

compositions using dorzolamide and hydroxyl ethyl cellulose (HEC) in combination with timolol sterilized via aseptic filtration. In another embodiment, the present invention relates to methods of manufacturing pharmaceutical formulations for topical administration that include a therapeutically effective amount of carbonic anhydrase inhibitor or ophthalmologically acceptable salts thereof, as well as a therapeutically effective amount of hydroxyl ethyl cellulose (HEC), for the treatment of ocular hypertension and glaucoma, where the said ophthalmic pharmaceutical formulation is free of benzene. Figure 2 depicts the mechanism of ocular Nano-systems uptake. Various ONS are available.

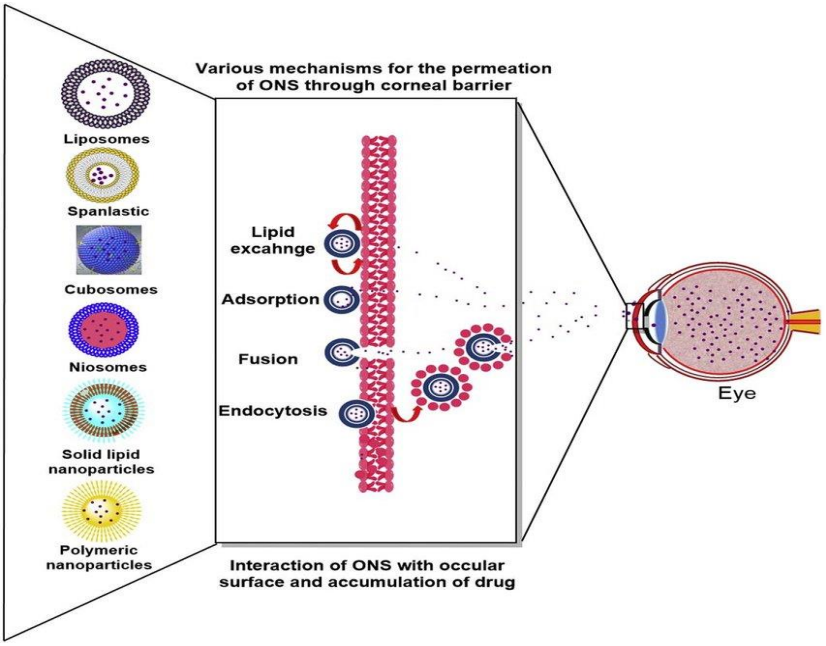

Figure 2: Mechanism of uptake of ocular Nanosystems. Various ONS
(Add result and dicussion)

Conclusion

Patients with burning, watery, and irritated eyes are all too common in clinics. It's crucial to examine the impact of preservatives in IOP-lowering solutions on the ocular surface, especially in patients with a history of dry eye illness (see Watch It Now). Reduced preservative burden may help with adherence, quality of life, and the patient-doctor interaction. There are a number of BAK-free preserved medicines and preservative-free goods to choose from. These topical treatments have been shown to increase ocular tolerance without lowering effectiveness.

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