

Effect of Different Sterilization Processes on Drug Loaded Silicone-Hydrogel

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Abstract : The sensitive nature of soft biomaterials, such as hydrogels, renders their sterilization a particularly challenging task for the biomedical industry. Widely used contact lenses are now studied as promising platforms for topical corneal drug delivery. However, to the best of the authors knowledge, the influence of sterilization methods on these systems has yet to be evaluated. The main goal of this study was to understand how different pairs drug-hydrogel would interact under an ozone-based sterilization method in comparison with two conventional processes (steam heat and gamma irradiation). For that, Si-Hy containing hydroxyethyl methacrylate (HEMA) and [tris(trimethylsiloxy)silyl]propyl methacrylate (TRIS) was produced and soaked in different drug solutions, commonly used for the treatment of ocular diseases (levofloxacin, chlorhexidine, diclofenac and timolol maleate). The drug release profiles and main material properties were evaluated before and after the sterilization. Namely, swelling capacity was determined by water uptake studies, transparency was accessed by UV-Vis spectroscopy, surface topography/morphology by scanning electron microscopy (SEM) and mechanical properties by performing tensile tests. The drug released was quantified by high performance liquid chromatography (HPLC). The effectiveness of the sterilization procedures was assured by performing sterility tests. Ozone gas method led to a significant reduction of drug released and to the formation of degradation products specially for diclofenac and levofloxacin. Gamma irradiation led to darkening of the loaded Si-Hys and to the complete degradation of levofloxacin. Steam heat led to smoother surfaces and to a decrease of the amount of drug released, however, with no formation of degradation products. This difference in the total drug released could be the related to drug/polymer interactions promoted by the sterilization conditions in presence of the drug. Our findings offer important insights that, in turn, could be a useful contribution to the safe development of actual products.

Keywords : drug delivery, silicone hydrogels, sterilization, gamma irradiation, steam heat, ozone gas

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