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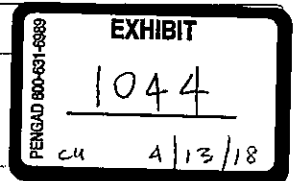
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Preservative Efficacy Of A New Lubricant Eye Drop Without Traditional Preservatives

R.A. Rosenthal; B.A. Schlech; S.L. Buck

+ Author Affiliations & Notes

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Abstract

Purpose: : Products provided in multi-dose containers must be adequately preserved in order to prevent contamination during repeated use. Traditional preservatives can cause irritation to the eye, but a product without preservatives may potentially become contaminated during use. The purpose of this study was to compare a new lubricant eye drop formulation to several marketed tear products.

Methods: : SYSTANE® Free Lubricant Eye Drops, a new tear formulation, was compared to marketed tear products by a method based on the United States Pharmacopeia preservative effectiveness test. The new eye drop formulation contains no traditional preservatives. Its preservative performance is based on a balanced composition of commonly used buffers and ions. The marketed products tested included preserved products: GenTeal artificial tears (Novartis, sodium perborate), Refresh Tears eye drops (Allergan, oxychloro complex), and Soothe emollient eye drops (Alimera, polyhexamethylene biguanide). The products were challenged with bacteria (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Escherichia coli*), and fungi (*Candida albicans* and *Aspergillus niger*) and sampled for survivors at 7, 14, and 28 days post inoculation. The number of survivors was determined using standard microbiological dilution pour-plate techniques.

Results: : The results showed that the new eye drop formulation and the marketed products tested met the USP preservative efficacy standards. Previous studies showed that the new eye drop formulation also met ISO preservative efficacy standards. All four products showed greater than a 3-log reduction of the challenge bacteria throughout the

each sample time. In addition, all products tested showed substantial anti-fungal activity. The new eye drop formulation showed approximately a 3-4 log reduction of the two challenge fungi by day 28.

Conclusions: : The results demonstrate that the new eye drop formulation, SYSTANE Free, was comparable in preservative efficacy to marketed tear products (Soothe, Refresh Tears, or GenTeal). Moreover, SYSTANE® Free Lubricant Eye Drops has good preservative efficacy and prevents contamination of the product.

Keywords: cornea: tears/tear film/dry eye • microbial pathogenesis: experimental studies • Staphylococcus

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