

Chapter IV

DISCUSSION

According to indications for use of each preparation, the samples used were classified in this test to be two groups. One of them was a group of eye drops with antimicrobial agents, with or without preservatives, indicated for use with infected eyes. Another was a group of preparations used for cleaning irritated eyes, in which preservatives were included in the preparations.

In the first group, eight samples were sulfacetamides preparations, seven samples were chloramphenicol containing and five samples were neomycin in combination with dexamethasone. Samples of this group may be prepared with or without preservatives, unlabeled, except in Sample No. 2. Normally all antimicrobial agents have also preservative properties to some organisms, but sometimes preservatives are needed to cover wide range of protection to contaminating microorganisms.

Chloramphenicol and aminoglycoside antibiotics are used to treat various infections, especially from gram negative bacteria. Sulfacetamide is one of synthetic sulfonamide derivatives. For ophthalmic preparations, it is used as a sodium salt. Generally it is an active antiinfective agent used in treatment of many diseases. In this test, sulfonamide-containing eye drops, with or without the

preservative, were completely protected from microorganisms challenging. This effective protection may be due to the drug effects, preservative effects, improper conditions for growth of contaminated microorganisms, or combination of these effects.

All antimicrobial preparations tested here were found to be effective against the microorganisms used in the test. Again, the second group samples were found to be effectively protected by the preservatives used. All preparations obtained ability to destroy contaminating microorganisms within seven days of the test period, except in sample No. 11, 13, 14, and 15 in which Candida albicans were found on seventh day, but were not found on the fourteenth day. Therefore, new containers of these samples, the Sample No. 24 to 50, were further diluted to 1:2 and 1:10 dilutions and were tested again for the effectiveness.

Benzalkonium chloride is a preservative which effective to most of gram positive organisms, while chlorobutanol and organomercuric compounds have broad spectrum action against gram positive and gram negative bacteria, and have also antifungal activities. Boric acid is a very weak germicide but can be used in wide range because it is nonirritating (42). It can be used on the cornea without ill effects (42). It seems to be in common that boric acid is included in almost all preparations of eye lotions and eye drops used for irritated eyes.

The results obtained from diluted samples are surprising. All samples were found to be in good preservation, eventhough they

were diluted ten times, except the sample No. 35 to 37 which ability against some organisms were not as good as the original ones. These may be because the preservatives were diluted to the concentrations lower than their active concentrations.

The results of diluted samples from this study cannot be the conclusive of preservative concentrations used as being thought, because to dilute the samples means to lower also the concentrations of all composit ingredients, not only the preservatives used. It means that original conditions of the preparations tested were not maintained in the test. If we want to check for effective concentrations of preservatives used, the sample must be checked with the same amounts of other ingredients. Only preservative concentrations must be varied. In this test, samples were obtained from markets and manufacturers. They were tested using the original containers obtained, as the propose of challenge testing of preservative effectiveness inwhich the final products containers must be inoculated with the test organisms. Therefore, diluted samples with varied amounts of preservatives but the same amounts of other ingredients could not be obtained. Self-prepared samples with constant composit ingredients, in the laboratory, would not yield the samples having same conditions as the marketed samples. So these samples were not prepared in the laboratory for this study.

From the samples used, amounts of preservatives were varied in rather wide ranges. Boric acid was used in concentrations of 0.2 % to 24.0 %. Chlorobutanol was used in concentrations of 0.003 % to 0.5 % , benzalkonium chloride was in concentrations of 0.000002 %

to 0.004 % , and organic mercurials were used in concentrations of 0.001 % to 0.003 % . But the results showed the same conclusion, the preservatives used were effective. This means we can use the lower concentrations of preservatives which yield the effectiveness in the preparations. Amounts of preservatives used are up to other compositions and other preservatives combination used in the preparations, and ought to be tested for effectiveness prior to distribute in the markets, especially the new products. Then we will have pharmaceutical products with effective preservatives in necessary amounts, not too excess ones, and then adverse effects from some preservatives will also be in low chance.



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