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Original Article

Evaluation of antimicrobial effectiveness of ophthalmic drops according to the pharmacopeial tests criteria

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Abstract:

ABSTRACT

Background: In this study antimicrobial effectiveness test was performed on eye-drops which had high microbial contaminations in hospital practice to find out whether their antimicrobial efficacies affect the magnitude of microbial contamination during their uses.

Materials and Methods: Artificial tear, atropine sulfate, betamethasone, homatropine hydrobromide, phenylephrine hydrochloride, phenylephrine zinc, pilocarpine hydrochloride, tetracaine hydrochloride and tropicamide eye-drops were subjected to the United States Pharmacopeia (USP) and British Pharmacopeia (BP) antimicrobial preservative effectiveness tests.

Results: The results of this study showed that eight out of the nine products met the BP 'B' and USP criteria. The preservative employed in phenylephrine zinc eye-drop did not possess adequate antimicrobial activity against *P. aeruginosa*. Other eye-drops showed appropriate reductions in bacterial viability after 6 hrs, 24 hrs and 7 days, but showed a very low bacterial recovery after 28 days which didn't comply with the no recovery (NR) term of BP 'A' criteria. Since viable microbial counts were usually determined by plate count method, it seems that the term of NR should define an acceptable range.

Conclusion: The results indicated that there is not a clear correlation between antimicrobial efficacy testing of eye-drops and the rate of their microbial contamination while are being used. Other factors such as hygienic practices of eye-drops, proper bottle design and training of patients could influence their microbial contaminations. Regulation of in-use efficacy testing of eye-drops which is influenced by the environment, the frequency and technique of use, might be essential

Keywords:

Antimicrobial effectiveness test, challenge test, preservative, eye-drop, ophthalmic drop

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