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Research Paper

MICROBIOLOGICAL QUALITY OF EYE DROPS SOLD IN OWERRI

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The Microbiological quality of the following eye drops, gentamicin, chloramphenical, ciloxan and sulphacetamide was studied. Gentamicin, chloramphenicol and ciloxan products were sterile while sulphacetamide products were contaminated by *Staphylococcus* spp (16.7%) and *Bacillus* spp (66.7%). The mean aerobic count found in sulphacetamide was 3 x 10^{2-} cfu/mL. This observation probably implies that eye drops sulphacetamide products could cause more health risk. However, hygienic practices of eye-drops, proper bottle design and training of patients could influence their microbial contaminations.

Keywords: Microbiological quality, Eye drops, *Staphylococcus*, Mean aerobic count

INTRODUCTION

Pharmaceutical products are generally grouped into two broad groups namely sterile and non-sterile products. Non sterile products obviously differ from sterile products in that they are permitted to contain some microorganisms (Samadi *et al.,* 2009). However, there is a specified maximum concentrations of microorganisms acceptable in different types of product and the species of organisms that are not permitted at all. Microbial contamination may lead to product degradation or result in ocular infection. The protection of these multiple dose products against microbial contamination is usually achieved by addition of a suitable preservative Sterility in sterile products is an absolute requirement (Schein *et al.,* 1992). Thus the presence of one single surviving microbial cell is sufficient to render the product non-sterile. For this group of pharmaceutical product, there is not a level of survivors which is so small as to be regarded as negligible and therefore acceptable.

Microorganism forms an integral part of our environment and there is considerable potential for microbes to enter medicines during both process manufacture and use. In this situation, it is not surprising that whenever non-sterile preparations and their ingredients are screened for microbial contamination, organisms are detected (Furrer *et al.,* 2002). The situation is very different for sterile preparations in the detection of any microorganism represent an unacceptable

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situation usually indicative of a breakdown in the sterilization process (Akerle *et al.,* 2002, Aulton, 2002; Bloomfield, 1990).

It is now realized that the presence of microorganisms in pharmaceutical preparation may have a variety of consequences, ranging from the negligible to the very serious. For example, spores of the mould, Mucor, may be present in a dormant form and never produce spoilage or harm the patients who takes the medicine (Kallings *et al.,* 1996, Khante, 1979). On the other hand, the presence of Salmonella in a medicine which, although causing little or no visible spoilage, would represent a serious hazard (Lamikara, 1988).

The instance in which there have been serious consequences attending contaminations have been in the main, concerned with those preparations which are required to be supplied sterile. This might be anticipated, as sterile preparations are usually administered parenterally or into the eyes and in these circumstances extraneous micro-organisms present a particular danger. Preparations for ophthalmic use have been responsible for serious infections of the eye, some resulting in blindness, as a result of microbial contamination. The objective, therefore, of this research work is to investigate the microbiological quality of some pharmaceutical eye drops sold in Owerri.

MATERIALS AND METHODS

Media

The following media, Nutrient agar, MacConkey agar, Mannitol salt agar, peptone water, Simmon's citrate agar, Sugar fermentation media were used for the isolation, purification and identification of microbial isolates. They were prepared according to the manufacturer's specifications and as described by Cheesbrough (2000).

Samples

The eye drops used for this work were purchased from patent medicine stores and pharmaceutical shops in Owerri. The brands of eye drops purchased include; chloramphenicol, gentamicin, Sulphacetamide and Ciloxam Eighteen eye drops (four of each brand except for sulphacetamide of which six were used) constituted the sample size in the study.

Sample Analysis

The samples were serially diluted upto 10^{-3} using the ten-fold serial dilution method (Cheesbrough, 1984) 0.1 ml of appropriate dilutions was inoculated onto sterile nutrient agar, MacConkey agar and Mannitol salt agar plates using the spread plate method. The plates were incubated at 37^0c for 24 to 48 h. At the end of the incubation period, the plates were counted and after careful examination, representative colonies were picked and subcultured onto sterile nutrient agar plates and incubated at 37^0C overnight for purification. Purified cultures were stored on nutrient agar slants and refrigerated.

Identification of Isolates

The pure culture of each isolates were identified according to standard procedures (Cowan, 1974). The following tests were employed.

a. Gram reaction

b. Motility

c. Catalase test

d. Coagulase test

e. Indole

f. Citrate utilization test

g. Methy-Red test

h. Voges proskauer test

i. Sauger fermentation test.

RESULTS

The results of the microbiological examinations of four brand of eye drops, namely, gentamicin, chloramphenicol, ciloxam and sulphacetamide sold in Owerri are shown in Tables 1 and 2. Table 1 shows the incidence of different bacterial isolate in the eye drops. Gentamicin, chloramphenicol and ciloxan eye drops were sterile while sulphacetamide was contaminated by *Staphylococcus* and *Bacillus* spp. Table 2 should the viable counts of the isolates.

DISCUSSION

In injections, eye drops and certain dressings and lavage solutions, sterility is essential since any contaminant may cause infections and the products of contaminants (pyrogens) have caused harmful and even lethal reactions. This study showed a total aerobic count of $3x10^2$ cfu/mL in one of the eye drops studied, (namely sulphacetamide), Table 2. Out of the six samples of this particular eye drop product, five were contaminated (Table 1, appendix). This indicates a potential hazard to the public. Such preparation for ophthalmic use could be responsible for serious infections of the eye, even resulting in blindness as a result of microbial contamination. The presence of microbes in such preparation is indicative of poor manufacturing particular eye drop product a*re Bacillus* spp. and *Staphylococcus* sp (Mehrgan *et al.,* 2006). The presence of these organisms suggested environmental contamination and ineffective sterilization technique. Other workers have also isolated these organism in some sterile pharmaceutical products (Ekka *et al.,* 1987). Eka *et al.* (1987) in their study of survival of microorganism in sterile pharmaceutical product

Table 1: Incidence of Different Bacterial Isolates in Eye Drop Products

Isolates	Gentamicin N=4 N(%)	Chloramphenicol N=4 N(%)	Ciloxan N=4 N(%)	Sulphacetamide N=6 N(%)
Staphylo-	–	–	–	1(16.7%)
Coccus spp				
Bacillus spp	–	–	–	4(66.7%)

Table 2: Mean Bacterial Count of Isolates from Different Eye Drop Brands Sold in Owerri

Eye drop Brands	Total aerobic count (cfu/ml)	Coliform Count(cfu/ml)	Sulphacetamide count(cfu/ml)
Cloramphenicol	–	–	–
Gentamicin	–	–	–
Ciloxan	–	–	–
Sulphacetamide	$3x10^2$	–	$1x10^1$

found these organisms to survive in the infusion fluids they studied. Hygienic practices of eye-drops especially in the hospitals, proper bottle design and training of patients could influence their microbial contaminations (Fazeli *et al.*, 2004).

In view of the contamination of sulphacetamide eye drop in Owerri market, there is the need for appropriate government agencies to regularly investigate pharmaceutical products for their microbiological qualities and to rid the market of such poor and contaminated products. This will help protect the public from the potential hazard such product will pose to the unsuspecting users.

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