



ANALYSIS OF PATHOGENS IN NONSTERILE PHARMACEUTICALS DRUGS OF PUBLIC HOSPITAL OF DAMAN (U.T)

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ABSTRACT

The generic Drugs are consumed on large scale used and prescribed by medical practitioner. There are number of generic drugs available in market in form of e.g., Soft Gilatine Capsule, Hard Gilatine Capsule and Tablets etc. Study was carried out by using various microbiological techniques to isolate and identify pathogens. From 20 drugs samples four isolates of *Escherichia coli* and five isolates of *Pseudomonas* and six isolate of *Staphylococcus aureus* were obtained. Thus it seems that genericdrugs samples may cause illness. Contamination of pharmaceuticals with microorganisms irrespective whether they are harmful or nonpathogenic can bring about changes in physicochemical characteristics of the medicines. Although sterility is not a requirement in official compendia for nonsterile pharmaceuticals, bioburdens need to be within acceptable limits. Therefore, this study investigated microbial contamination of 10 nonsterile pharmaceuticals frequently delivered to outpatients by identifying and quantifying microbial contaminants and susceptibility pattern testing on the microbes isolated.

Keywords:Pathogens, Non-sterile Drugs Products, Outpatients, Pharmacy, Bioburdens, Dispensing.

INTRODUCTION

Pharmaceuticals are used in a variety of ways in the prevention, treatment, and diagnosis of diseases. In recent years, manufacturers of pharmaceuticals have improved the quality of non-sterile pharmaceuticals such that today such products contain only minimal bioburden [1]. The occurrence of microbial contamination has been well documented, and contaminants range from true pathogens such as *Pseudomonas aeruginosa* [2]. Several reports have also been published describing clinical hazards that are attributable to microbiologically contaminated pharmaceuticals [3–5]. The major health concern is when such microbial contaminants exceed acceptable limits (10^2 cfu/mL) [6]. It must be stressed, however, that the majority of cases of medicine-related infections are probably not recognized or reported as such [7].

Solid dosage forms, mainly tablets and capsules, constitute a large proportion of medicines which are dispensed in Public hospital of Daman (U.T). Although many now are presented in blister packs, most developing

countries like India still have instances where such medicines are supplied in bulk containers, with the prescribed amount being drawn from these containers [8]. Mishandling may result in a serious health hazard following ingestion of highly contaminated drugs/solid dosage forms by patients whose immunity is already compromised by illness. The presence of microbes in drugs not only makes them hazardous from the infectious standpoint, but may also change the physical, chemical, and organoleptic properties of the drugs, alter the contents of active ingredients, or convert them to toxic products. Thus, a medicine may be considered microbiologically spoiled in this situation, depending on its intended use. The presence of even a low level of acutely pathogenic microorganisms, higher levels of opportunist pathogens, or toxic microbial metabolites that persist even after death of the original contaminants may render the product ineffective. Physicochemical deterioration as a consequence of microbial growth is a satisfactory reason to consider the product unsafe for human use [9].

MATERIALS AND METHODS

Sample collection and preparation of sample Dilution

In the case solid dosage form 10gm of sample were taken in a sterile Poly Bag and sterile disposable container in case of syrup. 10gm samples each of paracetamol, aspirin, vitamin B complex, and ferrous sulfate tablets, as well as indomethacin, doxycycline, and amoxicillin capsules, were randomly sampled from containers of 1000 tablets/capsules. Tablets, capsules, and syrups constitute a large proportion of the medicines on the market, are dispensed in all health facilities, and are prone to microbial contamination under improper storage conditions.

The selected drug samples are representative products that are readily available and most commonly used in the community. Two sample bottles each of Glycodin® cough syrup (Alembic, India) were also randomly picked from the shelves. Two 100 ml aliquots of Eusol (Edinburgh University solution of lime, liquid disinfectant) were also drawn from a large vessel which was used for extemporaneous preparation of the disinfectant. Label information (batch number, expiry date, manufacturing date, directions for use, and ingredient composition) was recorded. The collected samples of each brand were ground and/or dispersed in 90 ml of sterile Soyabean Casein Digest Broth. Similarly, 10 mL of the cough syrup was dispersed in 90 ml of sterile Soyabean Casein Digest Broth. All dispersions were left to settle for five minutes to dislodge possible microbial cells and to separate the solid particles and supernatants to be used in further tests. Sterile Soyabean Casein Digest Broth of same media lot was used as a negative control.

Pathogenic Detection

The diluents of Soyabean Casein Digest Broth containing sample were kept for enrichment of 24 hours at 30-35°C for further detection of pathogens. The samples were tested for pathogens such as *Escherichia coli*, *Staphylococcus Aureus*, *Salmonella typhi* and *pseudomonas aeruginosa* respectively.

1) For *Escherichia Coli*-the enrich sample 1 ml was transfer to MacConkeys Broth for streak a loopful of enriched MacConkey's broth on the surface of MacConkey agar plate.

2) *Salmonella typhi*-0.1 ml of enriched Soyabean Casein Digest Medium to 10 ml of Rappaport Vassiliadis *Salmonella* Enrichment Broth and incubated at at 30°C to 35°C for 18 to 24 hours. Enriched Rappaport *Vassiladis Salmonella* Enrichment Broth on the surface of sterile Xylose Lysine Deoxycholate Agar.

3) *Pseudomonas aeruginosa*- Enriched Soyabean Casein Digest Medium and streaked on the surface of Cetrimide agar medium plate.

4) *Staphylococcus aureus*: a loopful of enriched medium was streaked on the surface of Mannitol Salt agar plate.

5) *Candida albicans*: Enriched Saurburated Dextrose Broth was staked on the surface of Saurburated dextrose agar plate.

RESULTS AND DISCUSSION

The study findings have shown that all tested samples were microbiologically contaminated. The isolated aerobic bacteria were mainly *Bacillus* spp, while the fungal contaminants comprised and *Candida* spp. The acceptance criteria for pathogen in non-pharmaceutical products are should be absent. 6. But all samples were founded with five types of pathogens from the samples. This calls for more stringent measures to prevent possible detrimental effects. This is an indication of improper handling of pharmaceutical products in our hospital pharmacies, as already reported elsewhere [4]. The majority of the microorganisms isolated from the samples were normal human flora, which are widely distributed in nature [10]. This suggests that these medicines were microbiologically contaminated as a result of improper handling, poor hygienic procedures during repackaging into smaller packs, and dispensing of medicines. The presence of potentially pathogenic opportunistic microbes, including *C. albicans*, cannot be overemphasized, because they may cause a significant deterioration in the health status of patients, particularly those who are immunologically compromised, and of infants with an immature immune system [10,11].

The microbiologic quality of nonsterile solid dosage forms, like tablets, syrup is dependent on the bioburden of the process water and raw materials, both in the active ingredients and excipients [12], hence, the failure of strict observation of good manufacturing practice at any stage of production may greatly affect the microbiologic quality of the end products.

CONCLUSION

This study has revealed heavy microbial contamination in 50% of pharmaceuticals dispensed at hospital pharmacy. Poor handling of the pharmaceutical products during dispensing or repackaging might have contributed to the observed high rate of microbial contamination. Education on personal hygiene and proper handling of medicines in dispensers cannot be overemphasized, since these are essential for prevention and control of microbial contamination of pharmaceuticals and other medicine-derived infections.

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