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Research Article

Bacteriological Quality of Commonly Dispensed Non-prescription Drugs (Tablets) Sold in Patent Medicine Stores

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Abstract

Commonly consumed nonprescription oral dosage forms (tables) dispensed from Patent Medicine Stores are subject to unrestricted handling and potential contamination by microorganisms. We determined the bacteriological quality of tablets sold from patent medicine stores in Umuahia, Nigeria. A total of 113 items of 24 registered tablet brands were purchased. They were investigated for total bacterial count and presence of specified microorganisms using standard microbiological methods. Out of 113 items, 84(74.3%) tablets were free of microbial contamination while 14(12.4%) had bacterial counts $<10^2$ cfu/ml. Only 2(1.8%) tablets exceeded the specified bacterial limit of $>2x10^3$ cfu/ml. None of the blister-packed tablets had bacterial growth on them. All the tablets dispensed ("counted") from large containers were contaminated by aerobic bacteria. The commonly encountered bacterial contaminants were *Staphylococcus aureus* and *Bacillus species.* Folic acid and Magnesium trisilicate were the most contaminated tablets. The tablets in blister packs were of excellent bacteriological quality.

Keywords: Bacteriological Quality; Patent Medicine Stores; Commonly Dispensed; Non Prescription Tablets

Introduction

Medicines are an essential part of human life and the safety of medicine is of utmost importance in providing pharmaceutical healthcare needs of patients [1].

Non prescription drugs available in tablet dosage forms are subject to unrestricted handling and are therefore, potentially susceptible to post-production contamination by microorganisms. Analgesics and vitamin products are among the most commonly available non-prescription drugs and are therefore subject to unrestricted post-production handling [2].

Most of the raw materials for pharmaceutical products support some form of microbial growth due to their nutritive properties and moisture content. Hence, dry tablets that are prepared with these raw materials are capable of undergoing some form of microbial spoilage or degradation [1,3].

Patent medicine stores (PMS) are highly patronized in Nigeria and other developing countries because of low price of drugs, easy accessibility and low level of literacy of the populace [3]. These patient medicine stores are manned by quacks, who have no formal training in pharmacy.

The common practice of patent medicine stores, pharmacies, and retail pharmacies repackaging and dispensing bulk products into smaller dosage units increase product handling and the risk of microbial contamination from handlers and the environment [4]. Where dispensing hygiene is not good, in-use contamination can be gross [4].

The more serious problems of microbial contamination of tablets is where there are no obvious signs of spoilage and many cases of medicament related infections are probably not recognized or reported [5,6].

Oral dosage forms including tablets, although not required by most Pharmacopeia to be sterile, are nonetheless required to pass tests for the absence of certain specified microorganisms (*Escherichia coli, Salmonella* sp, *Pseudomonas aeruginosa, S. aureus* and *Candida albicans*) and microbial bioburden tests [7].

There has been paucity of reports of contamination of tablets dispensed from patent medicine store in Nigeria. This could be due to underestimation of health hazards to which patients are exposed through consumption of such tablets.

We therefore sought to determine the bacteriological quality of tablets dispensed from patent Medicine Stores in Umuahia, Nigeria.

Materials and Methods

Collection of tablet dosage forms

Twenty four different brands of tablet dosage forms were randomly purchased from 6 Patent Medicine Stores in Umuahia town, Abia State, Nigeria. Preference was for formulations with high public demand such as paracetamol, Diclofenac salt, Vitamin preparation and Magnesium trisilicate. All purchased drugs were manufactured by companies registered in Nigeria and their drugs approved by National Agency for Food and Drug Administration and Control (NAFDAC) for each brand, 3 packet and/or 30 "counted" tablets were obtained. A total of 113 units were tested.

Preparation of tablets dispersion

The blister of each brands of Ibuprofen Paracetamol and Diclofenac salt were swabbed with 70%v/v ethanol before opening. Similarly, the outside surfaces of containers containing Folic acid, Ascorbic acid, Ferrous sulphate and Magnesium trisilicate were also swabbed.

Five (5) tablets each of Ibuprofen, Ferrou sulphate, folic acid, Ascorbic acid and Diclofenac salt were dispersed in 10 ml sterile normal saline while 5 tablets each of paracetamol and Magnesium trisilicate were dispersed in 20 ml sterile normal saline. In general, 1g of each tablet was used Tablet dispersion was mixed in a Vortex mixer for 5minutes to dislodge possible microbial cells and allowed to stand for 30 minutes. A 1:10 sample dilution of each tablet was prepared using the supernatant of each preparation.

Bacterial enumeration

Bacterial enumeration tests were conducted according to the United States Pharmacopeia USP31 [8] using the spread on the dry surface of Plate Count Agar. Triplicates plates were done for each dilution. After incubation at 37°C for 24h, developed colonies from each plate were enumerated and the arithmetic mean count was used for calculating the viable count of the test sample in colony forming units unit / ml (cfu/ml).

Isolation of specified microbial contaminants

Tests for specified microbial contaminants were carried out according to the USP 31 [8] with some minor modifications. Aliquots from each diluted sample wassubcultured on Mannitol Salt agar, MacConkey agar and *Salmonella-Shigella* agar (Titan Biotechn Ltd, India) for the detection of *S. aureus, Pseudomonas aeruginosa, E. coli* and *Salmonella* sp respectively. After incubation at 37°C for 24h, the isolated colonies were Gram stained characterized and identified as previously described [9].

Results

Macroscopic examination of the different tablets indicates that they were neat, wholesome and unexpired.

Over 74% of the items tested were free from microbial contamination. Exactly 12.4% of the tablet dosage forms had bacterial counts of $2x10^2$ cfu/ml. Only 1.8% of the tablets had bacterial counts >$2x10^3$ cfu/ml (Table 1). USP31 specifies an acceptance criterion of a total viable count of not more than $2x10^3$ cfu/g or ml for non-aqueous preparations for oral use. It was therefore observed that only 2 tablets were found to exceed the specified bacterial limits.

Tablet	No of unit tested	No contamination free (%)	Level of bacterial contamination (cfu/ml)			
			<1.0 (%)	<200 (%)	200-2000 (%)	2000 (%)
Ibuprofen	12	12	0	0	0	0
Paracetamol	12	11	1	0	0	0
Diclofenac salt	9	9	0	0	0	0
Folic acid	20	13	4	3	0	0
Ascorbic acid	20	11	3	6	0	0
Ferrous sulphate	20	16	0	4	0	0
Magnesium trisilicate	20	12	4	1	1	2
Total	113	84(74.3)	12(10.6)	14(12.4)	1(0.9)	2(1.8)

Table 1: Distribution of bacterial counts in different tablet dosage forms.

Our results showed that none of the blister-packed tablets (Ibuprofen, Paracetamol and Diclofenac salt) had bacterial growth on them. However, all the tablets dispersed (counted) from large container (Folic acid, Ascorbic acid, Ferrous sulphate and Magnesium trisilicate) had growth of aerobic bacteria (Table 2). The bacteria isolated from the tablets includes *Bacillus* sp and *S. aureus. Bacillus* sp and *S. aureus* occurred simultaneously on Folic acid and Magnesium trisilictae while *S. aureus* was isolated from Ascorbic acid and Ferrous sulphate (Table 2). The results presented in table 2 showed that other USP 31 indicator pathogens, *E. coli, Salmonella* sp and *Pseudomonas aeruginosa* were not recovered from the tablet dosage forms.

Brand	No of units studied	Bacteria isolated
Ibuprofen	12	None
Paracetamol	12	None
Diclofenac salt	9	None
Folic acid	20	*Bacillus, S. aureus*
Ascorbic acid	20	*S. aureus*
Ferrous sulphate	20	*S. aureus*
Magnesium trisilicate	20	*S. aureus, Bacillus sp*

Table 2: Types of bacterial contaminants isolated from different tablet dosage forms.

Discussion

Microorganisms have been implicated in drug spoilage and the presence of certain microorganisms in nonsterile preparations may have the potential to reduce or even inactivate the therapeutic activity of the product [1,4,10]. Our findings have shown that 74.3% of the tablets tested were free from bacterial contaminants. Similar result was reported by Qasem., *et al* [7] in Jordan (72.7%).

Only 12.4% of the tested tablets harboured bacteria in counts between 10^2 and $<10^3$ cfu/ml. This observation falls within acceptance limit of the United States Pharmacopeia 31, an indication that all tested tablets were in conformity with standards in relation to microbial counts. It is also in agreement with 10.6% obtained previously [7,11]. These workers reported that out of 80 tablets dosage forms, 10% were contaminated with bacteria in counts ranging between 10^2 and 10^3 cfu/g.

All the tablet dosage forms were manufactured in Nigeria. This low microbial count indicates that the microbiological quality of these made-in-Nigeria products were adequate. It thus confirms the role played by the National Agency for Food and Drug Administration and Control (NAFDAC).

Microbial counts obtained from similar previous studies in Nigeria [3,12,13] indicated higher contamination rates where it was observed that out of all the tested products, none failed to grow microorganisms. This is in contrast to our findings. The recent enforcement by NAFDAC on Patent Medicine Stores and better adherence to current Good Manufacturing Practices by Pharmaceutical Companies in Nigeria account for the excellent result we obtained.

Tablets constitute a large proportion of the medicines dispersed from patent medicine stores. In our study, the blister-packed tablets did not harbor any bacteria whereas tablets "counted" from large containers were contaminated by bacteria. Contamination of blister-packed tablets does not occur after the blistering process. In modern dispensaries, tablets are now presented blister packs [7].

Dispensing of tablets from large packs is a common practice in patent medicine stores in Nigeria. It has been observed that the presence of contaminants on these "counted" tablets could be attributed to poor handling during dispensing, and/or repackaging and poor personal hygiene [4,14].

Bacillus sp and *S. aureus* were the major contaminants isolated from tablets counted to the patients. Similar result was obtained by previous studies conducted in Nigeria [3,13] and Dares Salam, Tanzania [15].

Ascorbic acid and Magnesium trisilicate tablets were mostly contaminated by *Bacillus* sp and *S. aureus* was the only indicator pathogen isolated. The presence of *S. aureus* as a contaminant reflects contamination of processing unit and/or raw material. The organism being a normal flora of the body easily contaminate products during handling and processing by personnel [16].

Bacillus species, a spore-former, was also commonly isolated from counted tablets. This is consistent with previous studies where majority of microbial contaminants in nonsterile pharmaceuticals was *Bacillus* sp [13,17,18].

Bacillus sp are ubiquitous and considered harmless, though undesirable because of their spoilage potential. Their presence in products suggest poor environmental hygiene during processing [15].

Two brands of Magnesium trisilicate, manufactured by a company had microbial counts >10^3 cfu/g. It showed that GMP was not observed in the company.

Conclusion

Commonly dispensed non-prescription tablet dosage forms sold in patent medicine stores in Umuahia, Nigeria, were of good bacteriological quality.

Blister-packed tablets were free of bacterial contaminants. Detected contaminants were due to poor handling during dispensing (counting) and/or repackaging. It is imperative therefore that all commonly dispensed, non-prescription tablet dosage forms be formulated in blister packets.

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