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Research Article

Physical and Microbial Examination of Commonly Sold Over the Counter Drugs, In Asaba Metropoly, Delta State

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Abstract: Contamination of over the counter drugs with micro-organisms whether they are harmful or non pathogenic can bring about changes in their physiochemical characteristics. Although sterility is not required in theofficial compendia for non–sterile pharmaceuticals, the bioburden needed to be within acceptable limit.Therefore, this study was carried out to determine the physical and microbiological quality of thenon-sterile pharmaceutical products. Nine(9) non-sterile pharmaceutical products were examined, six were cough syrups, three (3) were multivitamin syrups. Result showed that 66.7% (6 out of the 9 samples showed growth).Sample A was contaminated gram negative bacterium Pseudomonas species,sampleB, Pseudomonas species,sampleC Bacillus species,sample D Staphylococcus species, sample E, Escherichia coli,sample I staphylococcus species, while samples, F,G,H, had no growth. Though most of the sample microbial load fell within World Health Organization (WHO) recommendation, onlyone brand of cough syrup was heavily contaminated, even when it contained trisodium citrate as a preservative and thus did not meet the official limit. The lower count recorded in some cough syrups is attributed to the incorporation of trisodium citrate together with Sugar content of the syrups which provide high osmotic pressure that is inhibitory to many microorganisms The results showed that the samples tested had satisfactory microbial levels compared to the British Pharmacopeia specification of 103-104 cells per ml except for one of the sample. The most contaminated syrup had a viable count of 1.24 × 106 CFU/ml.
Keywords: drugs, contaminations, non-sterile, microbial, pharmaceutical

INTRODUCTION

Pharmaceuticals are used in a variety of ways in the prevention, treatment and diagnosis of diseases. In recent years, manufactures of pharmaceutical products have improved on quality of non-sterileproducts such that today, they now contain only minimal bioburden [5]. The occurrence of microbial contamination has been well documented, such as contaminates ranging from true pathogens (e.g. *Clostridium tetani*) to opportunistic pathogens (e.g. *Pseudomonas aeroginosa*) [2].

Cough is common among infants at various stages of development especially at the teething stage. This is because of the itching sensation produced by the gums; they pick any material ranging from toys to other objects to scratch the gum in order to relief such feelings. This can stimulate cough if they are contaminated with microbes which can cause inflammation and infection of the respiratory tract. Cough is also a common ailment during some specific times of the year (during summer season) especially among children [1].

From a microbiological view-point, only two types of medicinal product exist.Sterile medicinal product (they contain no viable and viable micro-organisms) and; Non-sterile medicinal product (they contain viable micro-organism). Although non-sterile products contain micro-organisms, they should not produce any injurious effect or degrade because of this contamination.

Consequently, non-sterile products contain preservatives that are designed to kill or limit the growth of any micro-organism that may gain entry into the product.

It has been reported that most drugs were contaminated by microorganisms during handling and storage [10]. Contamination of products may affect their stability causing product degradation prior to expiration date [1] and this can also lead to infections especially in the case of children, whose immunological system is weak.

The assessment of over-the-counter oral formulation is based on two features; the total number of micro-organism present and the type of micro-organism present. The presence of microbes in drugs do not only

make them hazardous form the infectious standpoint, but may also change the physical, chemical, and organoleptic properties of the drug, alter the potency of the active ingredients, or convert them to toxic product.Thus, a medicine may be considered microbiologically spoiled in this situation.

MATERIALS AND METHODS

Culture Media

The culture media used were, Nutrient agar (N.A), Peptone water and Sabourand 4% glucose broth.

Table 1: Cough and Multivitamin Syrup Used

Sl. No.	Sample Name	Constituents	Production Date	Expiry Date
1	Nomalyn Cough Syrup	Diphenythydramine hydrochloride B.P Tolu Syrup B.P Sodium Citrate B.P Menthol B.P	August 2011	August 2014
2	Tussylin Cough Syrup	Diphenythydramine HCl 7mg SodiumCitrate28.5mg Menthol 0.55mg	May 2011	May 2011
3	Tutolin Children Cough Syrup	Diphenythydramine HCl Ammonium Chloride Trisodium Citrate Citric Acid Menthol Flavoured syrup base	July 2011	June 2013
4	Emzolyn Cough Syrup for Children	DiphenythydramineHCl Menthol	March 2011	March 2014
5	Cofta	Ammonium Chloride Ipecacuanhaliq extract Liguorice extract BPC Peppermint oil Aniseed oil	June 2011	June 2013
6	Benylin for Children	DiphenythydramineHCl Sodium Citrate	July 2011	July 2014

Sample analysis

Samples were analyzed using pour plate methods to estimate the bioburden in accordance with Colin and Lyne[3]. The culture media was prepared according to manufacturer's instructions. Bacterial colonies were counted and the average in each case determined.

RESULT

Viable Count for Sample Preparation

A total of nine (9) brands were examined. Some of the samples showed no growth after 72 hours, while some others showed no growth after 24 hours.

Table 2:Showing the viable count for sample preparation

Sl. No.	Product Name	Dosage Form	No. Of Colonies. Dilution Factor	Bacteria Cfu
1.	NomalynA	Syrup	1 (10^{-1})	0.5 x 10^{2}
2.	TussylinB	Syrup	3(10^{-1})	1.5 x 10^{2}
3.	TutolinC	Syrup	39 (10^{-1})	1.95 X 10^{3}
4.	EnzolynD	Syrup	22 (10^{-1})	1.1 x 10^{3}
5.	CoftaE	Syrup	5(10^{-1})	2.5 x 10^{2}
6.	BenylinF	Syrup	248 (10-3)	1.24 x 10^{6}
7.	RanferonG	Syrup	Negative	-
8.	CawarontonicH	Syrup	Negative	-
9.	Afrab-viteI	Tonic	4 (10^{-1})	2 x 10^{2}

DISCUSSION AND CONCLUSION

The presence of microorganism (bacteria) of different species is in accordance to the fact the microorganisms are ubiquitous occurring in air, water and plant used in the preparation of these products. Pour plate method, a technique which favours the growth of aerobic and anaerobic bacteria was used in the investigation.

Findings from this study show that, some of the tested samples were microbiologically contaminated. The majority of the microorganisms isolated from the

sample were normal human flora which is widely distributed in nature. This suggests that themedicines were microbiologically contaminated as a result of improper handling, poor hygienic procedures during repackaging into smaller packs and dispensing of medicine.

The presence of potentially pathogenic and opportunistic micro-organism like *Staphylococus* species or other byproducts is not desirables. This calls for more stringent measures to prevent the possible detrimental effects.

The results showed that the samples tested had satisfactory microbial levels compared to the British Pharmacopeia specification of 103-104 cells per ml except for one of the sample. The most contaminated syrup had a viable count of 1.24 × 106 CFU/ml.

Four (4) groups of bacteria, *Bacillus subtilis, Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus*were isolated from the sample. The types of bacterial contaminants isolated suggest the route of contaminations possibly water, personnel and environment.

One brand of cough syrup was heavily contaminated, even when it contained trisodium citrate as a preservative and thus did not meet the official limit. This contamination can be attributed to poor manufacturing environment, water used or the personnel involved, packaging process or containers and equipments.

The lower count recorded in some cough syrups is attributed to the incorporation of trisodium citrate together with Sugar content of the syrups which provide high osmotic pressure that is inhibitory to many microorganisms [4].

From the results, some tested samples were contaminated with *B. subtilis.* Some recent studies have shown that *Bacillus* was the most frequent contaminant of non-sterile pharmaceuticals [6]. Members of this genus are widespread in the air, soil, water and in animal products such as hair, wool and carcasses [11].

The presence of *E. coli* in some of the samples indicated faecal contamination which may be principally from production personnel and possibly from the water used as vehicle. *Escherichia coli* are not always confined to the intestine and their ability to survive for brief periods outside of the body makes them an ideal indicatororganism to test samples for faecal contamination [11]. There was a reported incidence of infant diarrhea due to *E. coli* in some parts of Nigeria which resulted from the quality of water supply.

*Pseudomonas aeroginosa*which is a recalcitrant drug contaminant, and *Staph.aureus* were isolated from some samples. It has been reported that most liquid drugs were commonly contaminated by *Pseudomonas aeroginosa*[8]. The *Pseudomonas* contamination of this sample is of great public health significance to clinically available antimicrobial agents. Also *Pseudomonas spp.,* isolated from some bottled water and orange drinks were resistant to one or more antibiotics [7]. Some *Staphylococcus aureus* strains isolated from human wounds have been shown to be resistant to some antibiotics [9].

The major sources of contamination of pharmaceuticals have always been water, the production environment, the personnel and packaging material [12].

CONCLUSION

The results of the microbiological study of nine (9) brand of cough syrups and multivitamin preparations marketed in Delta State revealed that one (1) of the nine(9) preparations tested were highly contaminated above the official permissible limits of microbial load of non-sterile pharmaceutical preparations. It is therefore suggested that Good Manufacturing and Packaging Practice, proper treatment of water and air, personal hygiene improvement of the production personnel and pretreatment of natural raw materials be enforced and maintained. Also proper handling and storage of these products be carried out to eliminate or reduce microbial factors to ensure reduction in the level of microbial contamination. The incorporation of sufficient concentration of appropriate preservatives can also be employed to reduce the microbial load of these preparations. Good Manufacturing Practice cannot be overlooked in pharmaceutical industries, whether sterile or non-sterile preparations, as the health of the patients, in the case of children are of paramount importance. Drugs used in the treatment of cough and anemia cannot afford to be heavily contaminated. Children who take this medication have weakened immunological system already which makes them vulnerable to infections. Manufacturers should do their best to achieve 100% compliance and adherence to Good Manufacturing Practice.

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