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Microbiological quality of some herbal medicinal products sold in Accra, Ghana

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ABSTRACT

The aim of this study was to investigate the microbial quality of 10 different Herbal Medicinal Products (HMPs) sourced sampled from traditional medicine distributors and retail pharmacy outlets in Accra, Ghana. A total of 10 herbal medicinal products that were made for in vitro administration were randomly sampled in triplicates for analysis. Microbial Count was performed on the products. Isolation and identification various microbes from herbal medicinal samples were done also done. The results show that all of the products had their manufacturing and expiry dates stated, 5 (50%) products have been registered by FDB. The microbial load of the products varied considerably. The lowest microbial count was 2.2 $x10^3$ cfu/ml and the highest count was 6.2 $x10^3$ cfu/ml. Two (20%) of the products showed no bacteria growth. The predominant organism isolated was *Staphylococcus aureaus* and *Bacillus spp*. Only one sample had fungi isolate from it. However, *E. coli, Klebsiella spp* and *Salmonella spp* was not isolated in any of the 10 samples. There is need for constant monitoring and control of the standards of herbal medicines products in the Ghanaian market.

Introduction

Over the past decade, the use of herbal medicine/medicinal plants for medical treatments, has increased tremendously and has become increasing popular in both developing and develop countries (Eisenberg et al., 1998). Herbal medicines are often used to provide first line and basic health services to both the people living in remote areas where it is the only available health service and to people living in poor areas where it offers the only alternative medicine remedy (Reddy, Ansari & Shivkumar, 2000).

WHO has described traditional medicine as one of the surest means to achieve total health care coverage of the world's populationn pursuance of its goal of providing accessible and culturally acceptable health care for the global population (green paper). To this effect, WHO has championed the rational and responsible use of traditional plant based medicines, by member states and has developed technical guidelines for the assessment of herbal medicine (WHO, 1998; WHO, 2000).

Developing countries undoubtedly rely heavily on non-conventional medicines mainly of herbal sources in their primary healthcare (Akerele, 1993; WHO, 1998).

This is justifiable so because developing countries like Ghana has extraordinary richness of its flora, wide range of species. In the developing world, herbal medicine as an ultimate medicine has gained popularity because of typically low side effect profiles (Wilt et al.,2000), low cost (Vanderhoof, 2001) and high level of acceptance by patients and the majority of the population. Some managed care organizations now offer these therapies as an expanded benefit (Langyan &Ahuja, 2005).

In Ghana the uses of herbal medicine is premised upon high cost of the conventional pharmaceutical dosage forms, inaccessibility of the orthodox medical services to a vast majority of people particularly in the rural areas and the reservations by the public due to some reports , substandard or counterfeit drugs in the market.

Product quality is obviously the major criteria that could affect not only the efficacy but also the safety of patients or consumers of herbal products (Jutaputti, 2001). A numbers of identifiable problems are associated with the use of herbal medicines which include lack of precise dose and unhygienic method of preparation. Microbial contamination frequently involves in herbal products is not only as a result of unhygienic preparation but also from plants. Therefore, microbial contents in herbal products should be evaluated. This accounts for the reason why WHO has developed technical guidelines for the assessment of herbal medicine (WHO, 1998; WHO, 2000). These guidelines are important because, unlike chemically defined medicinal products, the biopharmaceutical quality and behavior of HMPs are often not well documented (European Agency for the Evaluation of Medicinal Products, 2003).

The WHO Good Manufacturing Practice Guidelines have provided technical guidelines to national regulatory authorities, scientific organizations, and manufacturers to undertake an assessment of the documentation/submission/dossiers in respect of herbal medicinal products.

In Ghana the food and drugs board is responsible for drug administration and control of the quality of medicinal products including generally available in the market.

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The aim of this study was to evaluate the microbiological quality of ten herbal products sold in Accra, Ghana. Undoubtedly the result from this research will provide vital information to encourage manufacturers, government agencies and policy makers in improving the quality of herbal products

Materials and Methods

Sample collection

A total of 10 herbal medicinal products that were made for invitro admiration were randomly sampled from traditional medicine distributors and retail pharmacy outlets in the greater Accra region of Ghana. The each product was collected in triplicate.

These samples were all in solution form and were intended to be administered orally. Products sampled included those that have been registered with the Ghana Food and Drugs Board as well as those not registered. The sample were transported on ice to the laboratory and stored at - 4^0C if analysis was not to be done immediately. The details of samples collected together with their therapeutic indications are presented in Table 1.

Microbial Count

Microbial count was done as follows: 1:10 dilution was prepared by dissolving or suspending 1ml of each sample in 9ml of 1% peptone water. Serial dilutions of each sample were made and viability assessed using the pour plate method. The plates were incubated at 37°C for 24h. The plate was placed on a colony counter and the number of colony forming units was counted. The microbial content was taken as the mean of duplicate determinations. Plate Count Agar (PCA, Oxoid) was used for bacteria count and Sabouraud dextrose agar was used for fungi count at 25°C for 72h.

Culture and Identification of Isolates

Identification of microbes from herbal medicinal samples was done by serially diluting in sterile 1% peptone water before plating onto appropriate media. For Staphylococcus *aureus* the sample was then streaked on Vogel- Johnson agar and incubated at 37° C for 24 hours. A single colony on each plate was then restreaked on Mannitol salt agar and incubated at 37° C for 24 hours. After the incubation, the colonial morphology was observed. For Enterobacteria, the diluted sample was streaked onto MacConkey agar plate. After the incubation at 37°C for 24 hours, the colonial morphology was observed. The colonies were sub cultured onto Triple sugar iron medium, Eosinmethylene blue agar, and Brilliant green agar for further characterization. Growth of bacteria was determined for Enterobacteria including *E. coli* and *Salmonella* spp. For *Clostridium* spp., the diluted sample was added into Cooked-Meat medium and incubated anaerobically at 37°C for 4 days. The growth of bacteria was examined regularly during the incubation period. The presence of *Clostridium* spp. was confirmed by colonial morphology and hemolytic reaction on blood agar plate. For *P. aeruginosa*, the diluted sample was streaked onto Cetrimide agar plate. After the incubation at 37°C for 24 hours, the green colonies were tested for oxidase reaction and subcultured into Triple sugar iron medium.

Glucose Yeast Extract Agar (OGYE) for yeast and moulds-Inoculated plates were incubated at 25^0C for a maximum period of 72hours. Conventional biochemical tests were performed on isolates leading to identification.

Discussion

All the ten (10) herbal medicine products selected for this study were liquid formulation. As shown in table 1 five of the herbal products has been registered with the FDB while five has not been registered. The Food and Drugs Board, Ghana is the national regulatory body under the Ministry of Health with the responsibility of implementing Food and Drugs Law of 1992, (PNDCL 305B) to regulate the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemicals with respect to ensuring their safety, quality and efficacy. It is mandatory for all drugs including herbal preparation to be registered and certified as product suitable for human consumption. All the five unregistered products were therefore not appropriate to be on the market.

From table 3, a total of five different organisms were isolated from the ten herbal preparations. The predominant microbial isolate was Staphylococcus aureaus with isolate count ranging from 2.2 -5.3 × 10^3. However, E. coli, Klebsiella spp and Salmonella spp was not isolated in any of the 10 samples. According to W.H.O guidelines, Salmonella, Shigella species and moulds must not be present in herbal medicines intended for internal use at any stage. The presence of any of these organisms in herbal products may indicate contamination during harvesting, production, transportation and storage as well as improper maintenance of good cold chain. Compliance with GMP is therefore crucial for the production of good quality herbal medicines. The entire production process, starting from cultivation and ending with the sale of the products, must adhere rigorously to GMP (WHO, 2007).

Herbs and herbal drugs may usually carry a large number of bacteria and moulds which include some of the organisms isolated in the herbal products under study. From Table 2, two samples representing 20% of the products used in the study had no microbial isolate while some of the products had as much as four isolates and this include fungi. Sample E and I (Table 3) had no isolate. Sample E is duly registered with the FDB and bore both content and therapeutic claim. Since Sample E had no isolate which presume that the herbal preparation was prepared in accordance with GMP. Although sample I had no isolate and bore its therapeutic claim, it did not bear the content and also not registered with FDB. Sample I is thus not a suitable herbal product for human consumption. With the exception of sample A and C which had 4 and 3 isolates respectively, 6 products had only one isolate.

Four organisms namely Staphylococcus aureus, Pseuduomonas aeruginosa, Bacillus Spp and Fungi were isolated from sample A (Table 2). It is also the only sample from which fungi was isolated. Isolation of fungus may be as a result of exposure of the product to air during preparation. Fungal growth was predominant and formed 40% of total microbial growth while Bacillus spp was 30%. Staphylococcus aureaus and Psedomonas aeruginosa formed about 15% each.

The predominant organism isolated was Staphylococcus aureaus and Bacillus spp. Staphylococcus aureaus was isolated in 5(A, C, F, G, J) herbal samples with microbial count ranging between 2.2 -5.3 × 10^3. Staphylococcus aureus may have been associated with touch contamination (Joyson et al., 1975).

Bacillus spp was also isolated in 5 (A, B, C, D, H) samples with microbial count ranging between 3.3-6.3 × 10^3. The primary sources of Bacillus spp are soil, water, dust, air, feces, vegetation, wounds and abscesses. The presence of Bacillus spp may indicate that the water used in the preparation of the product was not from a good source or the plant part used was the root which may contain soil.

Pseudomonas aeruginosa was isolated in 2(A, C) products. Microbial count ranged between 2.2-6.2× 10^3. Isolation of Pseudomonas aeruginosa in samples A and C may suggests that the root is a major part of the plants used in the preparation of the products. This is because Pseudomonas is primarily a soil bacterium and for it to be present in all the samples is an indication that the roots were not properly washed/treated before being used.

Conclusion and Recommendation

In conclusion it must be stated that herbal medicinal products have come to be part of the healthcare delivery system in Ghana. However Consumers can easily acquire pathogenic microorganisms by consuming contaminated herbal products.

The result from this study suggests that, all the organisms isolated had microbial count which was significant and can be a potential source of infection. So there is a need for the concerned regulatory authorities to make some provisions to regulate the preparation, use as well as sale of the herbal medicines. Safety, efficacy and quality of products play a vital role in curing diseases.

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Table 1: Product Code, Dosage Form, Content, FDB Registration, Country Of Origin, Manufacture And Expiry Date of some herbal medicinal products from Ghanaian market

Brand Code	Dosage form	Date of manu.	Exp date	Country of Manu.	FDB reg.no.	Contents	Therapeutic claim/ indication
A1,A2,A3	Liquid	2008	2015	Ghana	58732*	Karika papaya, Khaya ssenegalensis & ginger	Piles, waist pains, sexual weakness, constipation, removal of excess phlegm, stomach pains, improves eyesight, menstrual pains, headache, infertility, body pains, high fever and white, toothache
B1,B2, B3	Liquid	2010	2013	Ghana	FDB/HD.05/4020	Raufwolfia vomitoria, Xylopia aethiopica, Trichilia monadelph, Triplotaxis, stellulifera, Grosseria vignei, Anthocleisa nobilis Garcinia Kola, Spathodea companula, Honey	Piles, menstrual pains, anaemia, abdominal pain, lumbago, dyspepsia, purifies blood, enhances circulation
C1,C2,C3	Liquid	2008	2012	Ghana	none	Aloe -ferove, cassava slebeneena, panllina painnata, Piper guineese, Khaya	Relief of piles, constipation, waist pains, headache, fever, sexual weakness, fibroid, hernia
D1,D2,D3	Liquid	2010	2013	Ghana	FDB/HD.05-12102	Vernonia amygdalina, Kigelia africana, Anthocleisa nobilis, Combretodendron macrocarpum	Ordinary piles, bleeding piles, eyes itching, sexual weaknesses, menstrual pains, constipation, rheumatism
E1,E2, E3	Liquid	2010	2013	Ghana	AT/F92A*	Anthocleista nobilis, Combretodendron Macrocarpum, Khaya senegalensis, Ricinodendron heudelotii, Sorgumbicolor	Rheumatism, anaemia, menstrual disorder, loss of appetite, tiredness, general disability, piles, fevers
F1,F2, F3	Liquid	2009	2012	Ghana	BN-50,836C*	African aloe, Cassle sleberlana	Constipation, kidney related problems, asthma, sexual weakness, menstrual imbalances, removes phlegm, appetizer
G1,G2,G3	Liquid	2010	2013	Ghana	none	-	-
H1,H2,H3	Liquid	2009	2012	Ghana	none	-	-
I1,I2, I3	Liquid	2009	2015	Ghana	none	-	Loss of appetite, anaemia, general body weakness, rheumatism,
J1,J2, J3	Liquid	2010	2013	Ghana	none	-	-

= Not available/stated

Table 2 Microbial Count (cfu/ml) of Herbal Medicine Products

Sample Code	*Staph. aureus*	*E. coli*	*Pseuduomonas aeruginosa*	*Klebsiella Spp*	*Bacillus spp*	*Salmonella*	*Fungi*
A	2.2×10^3	-	2.2×10^3	-	5.7×10^3	-	6.2×10^3
B	-	-	-	-	6.1×10^3	-	-
C	2.2 x103	-	6.2×10^3	-	3.3×10^3	-	-
D	-	-	-	-	6.3×10^3	-	-
E	-	-	-	-	-	-	-
F	5.3×10^3	-	-	-	-	-	-
G	3.1×10^3	-	-	-	-	-	-
H	-	-	-	-	4.5×10^3	-	-
I	-	-	-	-	-	-	-
J	4.3×10^3	-	-	-	-	-	-

Table 3. Occurrence of bacteria isolates identified in Herbal Medicinal Products

Type of sample	NO. of samples	Bacteria isolated/occurrence (%)
A	3	*Staph aureus(15%) Pseuduomonas aeruginosa,(15%)Bacillus Spp(30%) Fungi(40%)*
B	3	*Bacillus Spp(100%)*
C	3	*Staph aureus(15%) Pseuduomonas aeruginosa,(55%)Bacillus Spp(30%)*
D	3	*Bacillus Spp(100%)*
E	3	ND
F	3	*Staph aureus(100%)*
G	3	*Staph aureus* (100%)
H	3	Bacillus Spp (100%)
I	3	ND
J	3	*Staph aureus(100%)*