QUANTITATIVE AND QUALITATIVE ASSESSMENT OF SELECETED HERBAL REMEDIES MARKETED IN NIGERIA

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ABSTRACT

There has been an upsurge in the consumption of herbal remedies due to its availability, increased popularity, poor medical services and inequalities in health service distribution in developing countries. However, regulatory and safety issues remain a concern. This study is aimed at assessing the concentration levels of some microelements and macroelements in NAFDAC approved herbal remedies, and also to assess the compliance of those products with national stipulated requirements for outer pack labelling. A total of ten (10) herbal products that are marketed in Nigeria were randomly purchased and analysed to determine the concentration levels of selected elements (Zn, Fe, Ni, Mn, Pb, Cd, Na and K) using AAS. The results indicated that Zn, Fe, Ni, Mn, Pb, Cd, Na and K have their own trends of concentrations in all the samples studied. Although all the samples contained Pb and Cd, the concentrations were below WHO permissible limits. Also, the assessment of the outer pack labelling of the products revealed that none of the samples complied totally with the national stipulated requirements. Conclusively, the study has shown that the quality and safety of herbal products needs to be regulated effectively before launching into the market.

KEYWORDS

Herbal remedies, macroelements, microelements, labelling, NAFDAC, AAS

INTRODUCTION

Herbal medicines are herbal preparations or products that contain parts of plants or other plant materials as active ingredients (WHO, 2008). In Nigeria, prior to the introduction of orthodox medicine, our people relied totally on the use of herbal remedies for all their health care needs (Isangadeghi, 2012). This dates back to the earliest history of mankind as it is in other cultures of the world (Ogunrin, 2012).

According to WHO (2008), about 80% of people living in the developing countries consumes herbal remedies. This is due to its popularity, availability, poor medical services, and gross

inequalities in health distribution in developing countries. Herbal medicine has impacted significantly on the lives of the people especially in rural areas where access to orthodox Medicare is minimal. Aside the lack of access, the prohibitive cost of some western medications makes herbal remedies more attractive.

Mineral elements are essential to the proper functioning of the body daily. These elements can be categorised into macroelements and microelements based on the recommended amount needed in the body daily (http.biomol.pl). Microelements are present in minute amount in the body many of which are essential in metabolism e.g. Zinc, Selenium. Macroelements are inorganic nutrient needed in relatively high daily amounts (i.e. more than 100milligram per day) e.g. sodium, potassium (Stedman, 2000). The consumption of herbal remedies contributes to the intake of these elements by the human body.

There is a general public perception that herbal medicines being natural are always free from adverse effects (Osakwe, 2012). However, regulations and scientific data about its effectiveness and mineral element content are poor; hence, there is a tendency that consumers of herbal products are subjected to great risks due to the probable presence of heavy metals in the products and non-disclosure of adequate information about the products (Oshikoya, Senbanjo, Njokanma & Soipe, 2008). Such information that may not be disclosed includes expiry date, dosage, contents, etc.

NAFDAC, the regulatory body for all drugs and food in Nigeria, is charged with the sole aim of assigning registration/listing numbers to these products. But most manufacturers are able to acquire a listing number which they brandish on the products for credibility, yet their claims of effectiveness have not been evaluated. The agency requires that a disclaimer be stated on the products to indicate such, yet most fail to do so.

As a result, this study aims to analyse the concentration of macroelements and microelements contained in some selected herbal medicines. This is to assess the safety of the products to ascertain their fitness for continuous use. It will also assess the compliance of those products with national stipulated requirements for outer pack labelling.

SAMPLE COLLECTION

Ten (10) selected brands of NAFDAC registered/listed herbal remedies were purchased randomly from mobile vendors, shops and distribution outlets (See Table 1)

SAMPLE PREPARATION

A nitric acid digestion technique was applied for wet digestion of the samples. The digested samples were kept in plastic containers and stored before the measurements.

SAMPLE ANALYSIS

Digested samples were analysed for Pb, Cd, Zn, Ni, Fe, Mn, Na and K using Atomic Absorption Spectrophotometer. All the measurements were run in triplicate for the samples and standard solutions.

RESULTS AND DISCUSSION
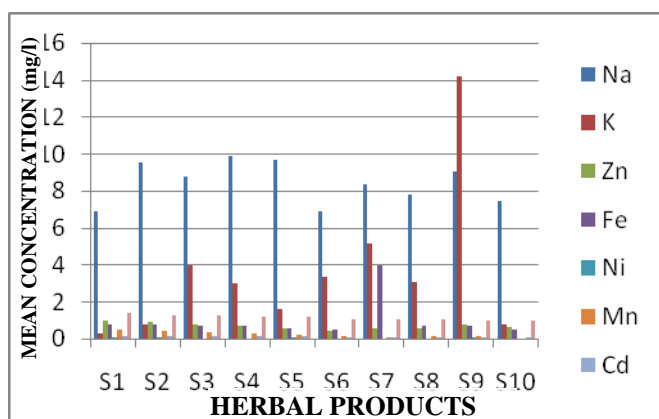
Figure 1: mean concentration of microelements in herbal products

Data reveals that Zinc concentrations in the herbal products varied from 0.45mg/l to 0.98mg/l. S6 had the lowest Zinc (Zn) concentration and S1 had the highest. Zinc concentration was the same in S5 and S7 with a value of 0.59mg/l. In all the samples, zinc was found in detectable limits. Zinc serves as a cofactor in many enzyme systems, including arginase, enolase, several peptidases and oxalacetic decarboxylases. It is believed to play a role in wound healing (http.biomol.pl). According to Medline plus, zinc intake should be less than 40mg per day while the recommended daily intake is 25mg. An overdose of zinc can lead to zinc poisoning.

The Iron (Fe) concentrations varied from 0.46mg/l to 3.97mg/l. S6 had the lowest iron concentration and S7 had the highest. Iron concentration was the same in S4 and S8 with a value of 0.68mg/l. Iron was detected in all the samples. Iron is an essential component of haemoglobin and myoglobin (Kay & Incekara, 2000). Its recommended intake level is 8-18mg in an adult. A slight deficiency in iron causes anaemia. Conversely, too much iron leads to production of harmful free radicals and interferes with metabolism (FNB, 2001).

Table 1: Contents and Therapeutic indication of selected herbal products

Brand Code	Herbal Product	Date of Manufacture	Expiry Date	NAFDAC No.	Content	Therapeutic Indication
S1	Oroki Herbal Mixture	09/14	10/16	A7-0642L	*Sorghum bicolour, Khaya grandifolia, Cassia sieberiana, Alstonia congnensis, Ocimum basillicum, Magnifera indica, Cyathula prostrata, Securidaca longepedunculata, Seccharum officinarum,* Water q.s	Pile, Dysentry, Constipation, diarhea, waist & stomach pain, worm, menstruation, turgidity
S2	Gangaria De Flush Herbal Mixture	01/08/14	01/01/15	A7-1296L	*Dolichos lablab, Khaya grandifolia, Securidaca longepedunculata, Citrullus colocynthis, Chrysophyllum albidum, Curciligo pilosa, Sorghum caudatum*	Pile
S3	Kogbebe Herbal Liquor	06/2014	06/2016	04-8326L	*Aleo barbaris, Aleo vera, Crestic ferruginea, Glycocalyx ollyophyllum, Tridas procunbens,* 15% Alcohol, Water	Sexual imbalance, weak erection, impotency, depressed sexual desire, premature ejaculation, low libido in both men & women and other sexual related malfunctions.
S4	Pakurumo Energy Booster	12/2013	10/2015	A7-1365L	*Crestic ferruginea, Glycocalyx ollyophyllum, Tridas procumbens,* 15% Alcohol, Water	Energy booster, vigor/vitality, pile, waist pain, etc.

S5	Koboko (Whip) Herbal Bitters	Not indicated	Not indicated	08-0266L	Active medicinal plant extracts	Vitality, strong erection, energy, eliminates menstrual pains, purifies blood formation.
S6	Kasapreko (Alomo) Bitters	04/02/14	Not indicated	A1-8029	Potable water, Ethyl alcohol (42%), Plant extracts, *Khaya Ivorensis, Capparis erythrocarpus, Lecaniodiscus cupanoides, Dialium guineese, Treculia africana, Flavours*	-
S7	HL-5 Regulator	November 2014	November 2016	04-8064L	*Khaya Iverensis, Cola giyanteam, Tetravera plifolia*	Stomach ache, poor libido, irregular menstruation, external and internal haemorrhoids, General body pains, chronic pile, eye infections, reduces sugar and fat in the body
S8	Kick & Start Man Power & Energy Booster	2014	2018	08-0648L	-	Diabetes, low sperm count, man extra power, pile, menstrual pain, gonorrhoea, Hypertension, body pain, wrist pain, toilet infection, stomach pain, energy booster.
S9	Eroxil 5000	Apr 2012	Mar 2015	A7-0263L	*Garcina cola, Pipernigrum, Zysigum aromaticum,*	Waist pain, digestion, reduces fatigue, increases

				Microdesmis puberula, Ephobia lateriflora, Uvaria chame, Securidaca longepedunculata, Treculia africana, Allium sativum, Zingiber officinale, water	energy & libido, nourishment to the heart, regulates blood level, reduces blood sugar, strengthens liver functions and kidney systems.
S10	Black Wood Bitters	Not indicated	Not indicated	B1-7529	Water, undenatured ethyl alcohol, plant extract *(Quashnida),* Glycerine, caramel, ethanol	-

Source: Author (2015)

The concentration of Nickel (Ni) was below detectable limits in S8 and S10. While the concentrations in the remaining samples varied from 0.02mg/l to 0.09mg/l. S6 and S7 had the lowest concentration and S2 had the highest. The concentration of Nickel in S1, S5 and S9 was the same with a value of 0.08mg/l. Nickel is required in minute quantities in the human body as it is mostly present in the pancreas and hence plays a critical role in the production of insulin. Its deficiency results in liver disorder (Kabata-Pendias & Pendias, 1992).

The Manganese (Mn) concentrations varied from 0.03mg/l to 0.52mg/l. The lowest concentration of manganese was found in S10, while S1 had the highest concentration. The concentrations of zinc were comparable in S7 and S8 with a range of 0.13 to 0.14mg/l, the same being true for S6 and S9 with a range of 0.18 to 0.19mg/l. Manganese is referred to as a humble trace element but it is essential to health. It enables the body to utilize some vitamins such as vitamin C and vitamin B1. It neutralizes free radicals and prevents diabetes. Its deficiency results in poor growth and birth defects (Samali, Kirim & Mustapha, 2012).

The Sodium (Na) Concentrations varied from 6.89mg/l to 9.88mg/l. S1 had the lowest concentration while S4 had the highest. In all the samples, sodium was found in detectable limits.

The concentrations of Potassium (K) ranged from 0.25mg/l to 14.16mg/l. S1 had the lowest concentration while S9 had the highest. Potassium was detectable in all the samples.

Sodium and Potassium are important for the proper functioning of vital organs in the body. They also play vital roles as structural and functional components of metalloprotiens and enzymes in living cells (Zaidi, Asrar, Mansoor & Farooqui, 2005). The recommended intake level for sodium and potassium are 1.5g and 4.7g respectively. High intake of sodium is a major contributor to cardiovascular disease (Aweng, Noor, Norashikin, Nur & Ahmad, 2014). Also excess or accumulated potassium in the body may lead to abdominal pains and intestinal ulcers (www.healthyeating.com).

The concentration of cadmium ranged from 0.07mg/l to 0.15mg/l. S10 had the lowest concentration and S1 had the highest. The concentration of Cadmium was the same in S4 and S5 with a value of 0.12mg/l, and also in S6 and S9 with a value of 0.09mg/l. In all the samples cadmium, a heavy metal was found in detectable limits.

The Lead (Pb) concentrations ranged from 0.97mg/l to 1.36mg/l. S9 had the lowest concentration and S1 had the highest. The concentration of Lead in S7 and S8 was the same with a value of 1.02mg/l. Lead, a heavy metal was found in detectable limits in all the samples.

Lead and Cadmium are heavy metals that are toxic to humans. They can be found in herbal medicines as a result of contamination or adulteration (Sayyed & Sayadi, 2011). When these toxic metals are found in high concentration in a product could to fatality if consumed (Agency for Toxic Substances, 2007). According to the WHO and other countries such as China,

Malaysia and Thailand, the permissible limits of Lead and Cadmium in finished herbal products is 10ppm and 0.3ppm respectively (WHO, 2005).

An analysis of the outer pack labelling information on the selected herbal remedies is summarized in Table 7. Only 90% of the samples indicated the manufacturer while S8 had no manufacturer's details. The NAFDAC registration number showed that 80% of the products had listed registration status (indicated by the "L" in the number), with only S6 and S9 having the full registration status. This means that the products with the listed registration status ought to carry a disclaimer notice to notify the public that their claims are yet to be evaluated by NAFDAC. However, the result of the analysis shows that only 25% (S1 and S2) of the listed samples carry a disclaimer notice while the larger percentage did not. S5 and S10 had no manufacturing and expiry date. Although S6 had a manufacturing date, it had no expiry date.

50% of the herbal products (S1, S2, S6, S9 and S10) had no indication for use on the outer pack label. A quantitative list of ingredients was absent on the label of S5 and S8. Batch number of the products was not indicated on S1, S5, S9 and S10. The dosage for use which is quite essential was indicated on the outer pack of only S7 and S9.

The results from this study have shown that there is an urgent need for the quality control of herbal products preparations. It has also emphasized the need for strict and continuous monitoring of the approved products by NAFDAC. As shown in Table 7, adherence of the selected herbal remedies to the stipulated labelling requirements of NAFDAC is not satisfactory.

CONCLUSION

Herbal products marketed in Nigeria contain a wide range of macroelements and microelements which are helpful in the maintenance of various functions of the human body. But most of these products did not strictly adhere to the NAFDAC labelling requirements. Also, toxic heavy metals were present in all the herbal products although in concentrations below WHO permissible limits. Therefore strict quality control guidelines and other stipulated laws concerning the safety of herbal products should be enforced by NAFDAC. Pharmacovigilance and safety monitoring of these products should also be ensured once they are listed or registered with NAFDAC.

ACKNOWLEDGEMENTS

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