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Heavy metals concentrations of traditional herbs consumed in Northwestern zone of Nigeria and associated health risks on humans

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Abstract

Herbal drugs have gained much popularity as alternative medicine among residents of the northern part of Nigeria, taking advantage of abundant medicinal plants in the region. This study therefore investigated the levels of some selected heavy metals (Cd, Hg, Ni, Pb and Zn) in five identified herbal drugs sold in Andaza town, Kiyawa local Government area of Jigawa State. Preparation of the samples was done using a wet digestion method with HNO_3 and HCl as digestion acids and the metals were determined using an atomic absorption spectrophotometer (AAS). The health risk assessment (HRA) for adults and children was done by using the estimated daily intake (EDI), target hazard quotient (THQ), hazard index (HI) and target cancer risk (TCR). The concentrations of heavy metals on dry weight (dw) basis in this study fell within the range (mg/kg dw, mean±SD)): Cd (0.156-0.312, 0.221±0.065), Hg (8.58-16.7, 12.7±3.78), Ni (0.960-2.74, 1.67±0.698), Zn (4.26-10.1, 6.17±2.34) and Pb (0.876-1.91). Pb was not detected in two out of the five samples and therefore the mean±SD of Pb was not computed. A comparison of the results with the World Health Organisation (WHO) maximum permissible limit showed that Hg levels were far above the permissible limit in all the samples; two samples had Cd values above the maximum limit. The concentrations of Ni, Zn and Pb in all the samples were within the recommended levels of WHO. Results of HRA showed that THQ were less than 1 in the analyzed metals except for Hg with relatively high values in both adults (70 kg body weight) and children (24 kg body weight) categories and this may pose a potential health risk to consumers. Results of the percentage non-carcinogenic risk (NCR) of each metal showed that Hg contributed more than 95% to HI (the overall NCR) in each sample. TCR of Pb indicates moderate to high cancer risk whereas, that of CD showed high to very high cancer risk if the samples are consumed for a long period of time. It is therefore important that consumption of these medicines should be monitored and regulated in order for consumers to avoid future health challenges.

1. Introduction

In recent times, the use of herbal drugs and other alternative medicines has been on the increase not only in Nigeria but across the globe, especially in preventing and managing some diseases such as rheumatism, hypertension, ulcer, cough, sexual impotency, headache and fertility among others. Unlike conventional drugs, herbal medicines are not usually subjected to regulation for purity and potency. As a result, negative effects connected to the toxic, heavy metals in herbal drugs are highly dangerous to human health (Somers, 1983). The nature and sometimes the source of these herbal drugs do make them susceptible to contaminations with heavy metals, toxins and even pesticides which could cause serious health problems for the consumers. Ingestion of heavy metals in contaminated areas could make them bioaccumulate in the body and this can cause health challenges such as disabled organs, retarded growth and immune deficiencies. Many people believe that herbal drugs are safe and could not cause any harm to humans due to their origin which is natural without any chemical modification. However, studies have shown that some of these herbal preparations are loaded with heavy metals beyond the limits set by regulatory agencies such World Health Organization (WHO) (Samali *et al*., 2017; Atinafu *et al*., 2015). Exposures to heavy metals by

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humans have been the main focus of attention among researchers, and health and nutrition experts due to their public health implications (Otitoju *et al*., 2012). Heavy metals could occur naturally as constituents of the earth's crust and could also be distributed through various activities of human beings. Heavy metals are non-biodegradable and could persist for a long time in the environment (Ara *et al*., 2018). Pollution of the environment by heavy metals, even at low concentrations, and their long–term cumulative health effects are among the leading global health concerns. Soil contamination by heavy metals can transfer to food and accumulate in consumers for instance, plants accumulate heavy metals from contaminated soil without physical changes or visible indication, which could pose a potential risk for humans and animals. Most of these heavy metals have long deleterious effects due to their non-biodegradable nature, and long biological half-lives and therefore have the capacity to accumulate in different parts of the body. Most of them are very toxic because they are soluble in water. They have harmful effects on human beings as well as animals even at low concentrations because the body finds it difficult to get rid of them (Singh *et al*., 2004; Chen *et al*., 2005).

Herbal medicine is gaining much popularity, especially among the local populations in developing countries of the world such as Nigeria. However, the quality, efficacy and safety of herbal medicines containing potential toxic metals have to be critically assessed before the products can be placed on the market (Wang *et al*., 1996). Traditional herbal medicine is an important but often underestimated health resource with many applications, especially in the prevention and management of chronic diseases and in meeting the health needs of aging populations (WHO, 2019).

The northern part of Nigeria is home to different kinds of herbs due to geographical location. However, few reports are available on the toxic heavy metals in herbal drugs produced and consumed in this part of the country. This study therefore is aimed at investigating the toxicity of lead, (Pb) mercury (Hg) zinc (Zn) cadmium (Cd) and nickel (Ni) in five herbal drugs available in Andaza town, Kiyawa Local Government Area of Jigawa State, Nigeria.

2. Materials and methods

2.1 Description of the study area

The map showing the location of the study area (Andaza town) is shown in Figure 1. Andaza is a popular town in Kiyawa Local Government Area of Jigawa State, Northwest, Nigeria, located on Latitude 11°24’ 26” N and Longitude 9° 27’ 40” E. Kiyawa Local Government has an estimated population of 200,845 inhabitants, majorly Hausa and Fulani ethnic groups. Islam is the religion widely practiced in Andaza town and the Hausa language is the main language of communication in the area. Agriculture is the major economic activity in Andaza village and the residents are predominantly farmers.

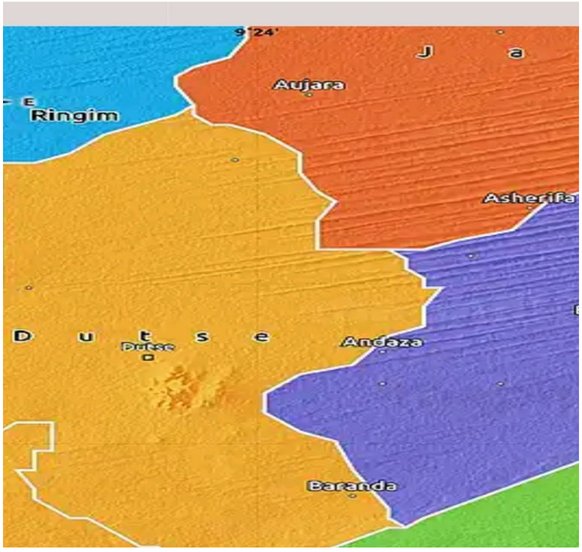

Figure 1. Map of the study area, Andaza area of Jigawa State, Nigeria.

2.2 Chemicals and laboratory equipment

All the chemicals used for the analysis were of Analytical Grade. The materials and the chemicals were ceramic mortar and pestle, analytical balance (Mettler Toledo, Switzerland), digital timer hotplate (Thermo Scientific, USA), Vortex shaker, different sizes of volumetric flasks (Pyrex, USA), different sizes of beaker (Pyrex, USA), Whatman filter paper (150mm diameter, GE Healthcare, USA), nitric acid (Sigma Aldrich product of United States of America), perchloric acid (Sigma Aldrich product of USA), distilled water and stock solutions of the metals obtained from Physical and Chemical Laboratories, N.I.M.G, Jos, Nigeria.

2.3 Sample description and preparation

The herbal drug samples in powdery form, sealed inside small polythene bags and then covered with sachet papers, were purchased from different shops in Andaza town, Kiyawa Local Government Area of Jigawa State, Nigeria. The samples were carefully removed from the seal with scissors, sieved separately using a 2 mm sieve to obtain fine particles and kept inside dry polythene materials prior to use for analysis. The samples were coded as HD-1, HD-2, HD-3, HD-4 and HD-5.

2.4 Samples digestion and analysis

Five grams each of dried herbal drug samples were weighed into digestion flasks, and 8 mL of trioxonitrate

(V) acid was added followed by 4 mL perchloric acid. The digestion flasks were then put on a hot plate at 80℃. The temperature was gradually increased to 120℃ until there was complete digestion. The digested samples were filtered and diluted with distilled water and made up to 100 mL (UNEP/FAO/WHO, 1992). Heavy metal concentrations in the samples (Pb, Hg, Ni, Cd and Zn) were determined using a Perkin Elmer PinAAcle 900H Atomic Absorption Spectrophotometer (AAS) facility from the Central Laboratory, Bayero University, Kano, Nigeria.

2.5 Health risk assessment

The following parameters were used to assess the non-carcinogenic and carcinogenic health risk of the samples: estimated daily intake, target hazard quotient and chronic hazard index.

2.6 Estimated daily intake of the heavy metals

The estimated daily intake (EDI) of heavy metals was calculated using the equation (Uddin *et al.*, 2019):

$$EDI = \frac{C_m \times R_f}{B_w} \quad (1)$$

Where C_m is the concentration of heavy metals (mg kg^{-1} dry weight), R_f represents the daily intake of food in kg per person per day (0.015 kg/person/day) and B_w is the average body weight in kg (24 kg for children; 70 kg for adults).

2.7 Non-carcinogenic risk

2.7.1 Target hazard quotient

The target hazard quotient (THQ) was calculated using the following formula (Uddin *et al.*, 2019):

$$THQ = \frac{EDI \times Ef \times De}{Df \times Tavncar} \quad (2)$$

Where THQ denotes non-cancer risks, Ef represents the exposure frequency (365 days $year^{-1}$), and De represents exposure duration (65 years); D_f denotes reference dose. D_f of Pb, Hg, Ni, Cd and Zn are 0.004, 0.0003, 0.02, 0.001 and 0.30 (mg/kg/day) respectively (US EPA, 2021) and T*avncar* represents the average time for non-carcinogens (365days $year^{-1}$ × De) (US EPA, 2011).

2.7.2 Chronic hazard index

The chronic hazard index (HI) is the sum of more than one hazard quotient for multiple toxicants or multiple exposure pathways (Ekhator *et al.*, 2017). This was calculated using the equation:

$$HI = \sum THQ \quad (3)$$

2.8 Carcinogenic risk

2.8.1 Target cancer risk

The target cancer risk (TCR) was estimated by using the formula by US EPA (2011):

$$TCR = THQ \times S_{epo} \quad (4)$$

S_{epo} = carcinogenic potency slope. Pb and Cd reference values are 0.0085 and 6.10 mg kg^{-1} bw day^{-1} respectively (US EPA, 2015).

2.9 Data analysis

The data analysis (Oloyo, 2001) was carried out using Microsoft Excel package.

3. Results and discussion

Table 1 presents the sample codes of the traditional herbs. The codes ranged from KD-1 – KD-5. Table 1 also shows the composition and various traditional uses of the samples. Some of the samples had one or two of their compositions similar to each other.

Table 1. Codes, composition and traditional use of the local herbal medicines.

Sample Code	Composition	Traditional use
HD-1	*Balanites aegyptiaca, Ziziphus mauritiana, Psidium guajava*	Malaria, yellow fever and abdominal pain
HD-2	*Ziziphus spina, Morning oleifera, Ziziphus mauritiana*	Breast cancer, skin cancer and leukemia
HD-3	*Perkia biglobosa, Balanites aegyptiaca, Psidium guajava*	Typhoid fever, malaria and vomiting
HD-4	*Ziziphus spina, Psidium guajava, Balanites aegyptiaca*	Cold, skin rashes and body inflammation
HD-5	*Moringa oleifera, Psidium guajava*	Body pain, headache and body weakness

The concentrations of heavy metals (mg/kg) are presented in Table 2. Mean values of cadmium ranged from 0.156-0.312 mg/kg. The highest concentration found in HD-4 (0.312 mg/kg) compared well with the 0.3 mg/kg maximum permissible limit set by WHO (2007); others were comparatively lower. The results of Cd in this study were lower than the following vegetables found in Bangladesh (mg/kg): spinach (0.44-0.85), kholrabi (0.32-0.96) and papaya (0.23-1.05) (Uddin *et al.,* 2019). However, Cd was not detected in herbal preparations in some parts of Ethiopia (Meseret *et al.*, 2020), Jordan (Alhusban *et al.,* 2019) and Bangladesh (Zamir *et al*., 2015). Cd is found to be carcinogenic at high concentrations. Accumulation of Cd in the kidney can cause renal track impairment, weak bones and lung problems (Mahurpawar, 2015).

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Table 2. Mean concentration (mg/kg dw) of heavy metals in local herbal drugs.

Sample ID	Cd	Hg	Ni	Pb	Zn
HD-1	0.180±0.001	9.37±0.065	0.96±0.012	ND	4.26±0.001
	0.179-0.181	9.304-9.434	0.949-0.972	NC	4.259-4.260
HD-2	0.264± 0.001	16.3±0.170	1.79±0.013	0.876±0.003	5.14±0.004
	0.263-0.265	16.350-16.490	1.778-1.803	0.872-0.898	5.135-1.143
HD-3	0.156±0.001	8.58±0.122	1.73±0.006	ND	4.90±0.003
	0.155-0.157	8.456-8.708	1.724-1.736	NC	4.898-4.903
HD-4	0.312±0.001	16.7±0.103	2.74±0.014	1.91±0.015	10.1±0.003
	0.311-0.313	16.589-16.808	2.726-2.754	1.896-1.924	10.095-10.101
HD-5	0.192±0.002	12.4±0.066	1.14±0.011	1.21±0.011	6.43±0.002
	0.190-0.194	12.320-12.460	1.130-1.150	1.198-1.222	6.427-6.435
Mean±SD	0.221±0.065	12.670±3.78	1.672±0.698	NC	6.166±2.34
CV%	29.4	29.8	41.8	NC	37.9
Range	0.155-0.313	9.304-16.808	0.949-2.754	0.872-1.924	4.259-10.101

ND: Not detected, NC: Not computed.

Concentrations of Pb ranged from 0.876 mg/kg in HD-2 to 1.91 mg/kg in HD-4. Pb was below the detection limit of the instrument (i.e. not detected) in HD -1 and HD-3. The results of this study were comparatively lower than the 10.0 mg/kg limit set by WHO for local herbal preparations. The results were also lower than the following literature reports (mg/kg): vegetables in some parts of Bangladesh (1.62–13.4) (Uddin *et al*., 2019); traditional herbal preparation in Northeast Ethiopia (3:00–4.00) (Meseret *et al*., 2020). Results of this study clearly showed that the samples Pb were within the permissible limit of 10.0 mg/kg. Similar results have been reported for herbal drugs consumed in Saudi Arabia (Maghrabi, 2014). Pb is known to be toxic and bioaccumulation in the body may result in vision impairment, kidney and brain damage and reproductive disorders. Therefore, Pb toxicity and poisoning should be avoided as much as possible (Dghaim *et al*., 2015). Concentrations of Hg in this study were high in the range of 8.58–16.7 mg/kg. The maximum limit set by regulatory agencies is (mg/kg): European Union (2006) (0.02); Chinese Department of Preventive Medicine (CDPM) (1994) (0.20) WHO/FAO (2007) (0.02). Each of the samples had a value far above these recommended maximum limits. This shows that the environment where the herbs were grown is highly contaminated with Hg. Transformation of inorganic mercury into methyl mercury, a lipophilic and biomagnified substance is usually achieved by microorganisms in aquatic environments. Hg is transferred from mother to fetus and infants through diets and breastfeeding respectively (Grandjean *et al*., 1995). This is a nutritional disadvantage as both the fetus and young children could be exposed to Hg toxicity even at low concentrations. Exposure to low concentrations of Hg has been discovered to cause decreased performance of motor functions and memory loss (Zahir *et al*., 2005), neurological disorder (Johnson and Yawson, 2000) as well as reproductive disorder (Anderson *et al*., 2004). High levels of Hg in the samples could be due to the nature of the soil and the environment where the herbs were grown. Mean concentrations of zinc in this study ranged from 4.26–10.1 mg/kg. These values were less than 10.4-38.9 mg/kg in some powdered herbal medicines in Lagos, Nigeria (Onwordi *et al.,* 2015). The results of this study were also below 50.0 mg/kg and 60 mg/kg maximum permissible limits by the Chinese Department of Preventive Medicine (CDPM) (1994) and WHO/FAO (2007) respectively. Zinc is one of the essential trace metals required by the body at low concentrations. Zn performs some positive functions in the metabolism of cholesterol and carbohydrates (Adesina *et al*., 2020). The concentration of Zn in this study will perform these biochemical functions. However, high levels of zinc in the body could have negative effects on the health of the consumer (Jarup, 2003).

Though nickel in trace amounts may be biochemically useful as it activates some enzymes in the body, the toxicity at relatively high concentrations is more pronounced (Ameen *et al*., 2019). According to WHO (1996), the maximum permissible limit for Ni is 10.0 mg/kg. The concentrations of Ni (0.960–2.74 mg/kg) fell within the permissible limit going by the above standard. The results of this study were lower than 10.45–39.25 mg/kg reported for contaminated vegetables from Varanasi, India (Singh *et al.,* 2010).

The results of estimated daily intake (EDI) for both adults and children (70 kg body weight, bw and (24 kg bw respectively) are presented in Table 3. The EDI for adults were (mg/kg/day): Cd (3.34E-5-6.69E-5) mean value = 4. 73E-5; Hg (1.84E-3–3.49E-3), mean value = 2.69 E-3; Ni (2.06E-4–5.87E-4). Mean value = 3.58E-4; Pb (1.88E-4–4.09E-4), mean = NC (not computed); Zn (9.13E-4–2.16 E-3). For children (24 kg bw), EDI levels were Cd (9.75E-5–1.95E-4), mean value = 1.38 E-4; Hg (5.36E-3–1.04E-2), mean value = 7.91E-3; Ni (6.00E-4–

Table 3. Estimated daily intake (EDI) of the herbal drugs for adults and children.

Sample	Adults (70 kg body weight, bw)					Children (24 kg body weight, bw)				
	Cd	Hg	Ni	Pb	Zn	Cd	Hg	Ni	Pb	Zn
HD-1	3.86 E-5	2.01 E-3	2.06 E-4	NC	9.13 E-4	1.13 E-4	5.86 E-3	6.00 E-4	NC	2.66 E-3
HD-2	5.66 E-5	3.49 E-3	3.84 E-4	1.88 E-4	1.10 E-3	1.65 E-4	1.02 E-2	1.12 E-3	5.48 E-4	3.21 E-3
HD-3	3.34 E-5	1.84 E-3	3.71 E-4	NC	1.05 E-3	9.75 E-5	5.36 E-3	1.08 E-3	NC	3.06 E-3
HD-4	6.69 E-5	3.47 E-3	5.87 E-4	4.09 E-4	2.16 E-3	1.95 E-4	1.04 E-2	1.71 E-3	1.19 E-3	6.31 E-3
HD-5	4.11 E-5	2.66 E-3	2.44 E-4	2.44 E-4	1.38 E-3	1.20 E-4	7.75 E-3	7.13 E-4	7.56 E-4	4.02 E-3
Mean	4.73 E-5	2.69 E-3	3.58 E-4	NC	1.32 E-3	1.38 E-4	7.91 E-3	1.04 E-3	NC	3.85 E-3
SD	1.39 E-5	7.80 E-4	1.49 E-4	NC	4.99 E-4	4.05 E-5	2.35 E-3	4.35 E-4	NC	1.46 E-3
CV%	29.4	29.0	41.8	NC	37.8	29.4	29.8	41.8	NC	37.9

NC: Not computed.

1.71E-3), mean value = 1.04E-3; Pb (5.48E-4–1.19E-3), mean value = NC; Zn (2.66E-3–6.31E-3), mean value = 3.85E-3. The coefficient of variation (CV%) was low (<45%) for each metal, showing the closeness of results. However, the mean value could not be computed for lead because it was below the detection limit in HD-1 and HD-3, showing that the two samples were not contaminated with Pb.

The carcinogenic and non-carcinogenic risk assessment for the consumption of herbal products is shown in Table 4. The target hazard quotient (THQ) (for adults and children respectively) was Cd (0.033–0.067 and 0.098–0.195); Hg (6.13–11.6 and 17.9–34.7); Ni (0.010–0.029 and 0.030–0.086); Pb (0.047–0.102 and 0.137–0.298); Zn (0.003–0.007 and 0.009–0.021). According to the New York State Department of Health (NYSDOH) (2007), if EDI/reference dose (RfD)≤RfD, the health risk will be very low; if EDI/RfD>1-5RfD, the risk will be low; if EDI/RfD>5-10RfD, there will be moderate risk; If EDI/RfD>10RfD, there will be high risk. In this study, the ratio of EDI/RfD was greater than RfD in each of the samples in both 70kgbw and 24kgbw categories for Pb. For Cd, it was greater in all samples (in both categories); for Zn, it was less than RfD in all samples in both 70 kg bw and 24 kg bw categories and for Ni, it was greater for all samples in 24kg bw and only HD-4 in 70 kgbw category. It is worthy of note that the ratio of EDI/RfD of Hg was more than a thousand times greater than RfD for all samples in both categories indicating high potential health risk.

The acceptable value for THQ, which measures the probability of having non-carcinogenic health issues is <1.0 (US EPA, 2011) and if the THQ value of any metal exceeds its permissible limit, it might cause non-carcinogenic health problems for humans (Ambedkar and Maniyan, 2011). The results of this study showed that the THQ of 4 out of 5 heavy metals (representing 80%) was less than the tolerable limit of 1.0. However, extremely high levels of THQ for Hg imply that it could pose non-carcinogenic health risks to consumers.

Hazard index, (HI) is known to be the combined influence of all heavy metals under consideration. HI value less than 1.0 implies that the combined effects of heavy metals could not cause long-term non-carcinogenic health problems for the consumers and values above might have adverse health challenges. HI levels in this study were well above 1.0 in both adults and children categories which is an indication of long-term non-carcinogenic health risk.

The levels of TCR in this study for 70 kg and 24 kg body weights were Pb: 0.001 and 0.001-0.003 respectively; Cd: 0.201-0.409 and 0.598-1.19 respectively. It has been reported that when TCR≤10^{-6},

Table 4. Target hazard quotient, hazard index and target cancer risk for adults and children.

Metals	Adults (70 kg bw)					Children (24 kg bw)				
	HD-1	HD-2	HD-3	HD-4	HD-5	HD-1	HD-2	HD-3	HD-4	HD-5
Cd	0.039	0.057	0.033	0.067	0.041	0.113	0.165	0.098	0.195	0.120
Hg	6.70	11.6	6.13	11.6	8.87	19.5	34.0	17.9	34.7	25.8
Ni	0.010	0.019	0.019	0.029	0.012	0.030	0.056	0.054	0.086	0.036
Pb	NC	0.047	NC	0.102	0.061	NC	0.137	NC	0.298	0.189
Zn	0.003	0.004	0.004	0.007	0.005	0.009	0.011	0.010	0.021	0.013
HI	6.75	11.7	6.19	11.8	8.99	19.7	34.4	18.1	35.3	26.8
$TCR_{(Pb)}$	NC	0.001	NC	0.001	0.001	NC	0.001	NC	0.003	0.002
$TCR_{(Cd)}$	0.238	0.348	0.201	0.409	0.250	0.689	1.01	0.598	1.19	0.732

HI: Hazard quotient, TCR: Target cancer risk, NC: Not computed

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Table 5. Percentages of non-carcinogenic risk of heavy metals in the herbal drug samples.

Metals	Adults (70 kg bw)					Children (24 kg bw)				
	HD-1	HD-2	HD-3	HD-4	HD-5	HD-1	HD-2	HD-3	HD-4	HD-5
Cd	0.578	0.487	0.533	0.568	0.456	0.592	0.480	0.541	0.552	0.458
Hg	99.3	99.1	99.0	98.3	98.7	99.7	98.8	98.9	98.3	98.5
Ni	0.148	0.162	0.307	0.246	0.133	0.152	0.163	0.298	0.244	0.137
Pb	NC	0.402	NC	0.864	0.679	NC	0.398	NC	0.844	0.721
Zn	0.044	0.034	0.065	0.059	0.056	0.046	0.032	0.055	0.059	0.050

NC: Not computed

there is low carcinogenic risk; when TCR $=10^{-5}$–10^{-3}, the carcinogenic risk is moderate; when TCR = 10^{-3}–10^{-1}, it implies high risk and when TCR$\geq10^{-1}$, the risk is very high (NYSDOH, 2007). In this report, the TCR of Pb will pose a moderate to high cancer risk whereas, the TCR of Cd will pose a very high cancer risk when the herbal drugs are consumed over a long period of time.

The percentage contribution of each metal to non-carcinogenic risk was computed and shown in Table 5. The percentages were in the range (%): Cd (0.456-0.578); Hg (98.3-99.3); Ni (0.133-0.307); Pb (0.402-0.864); Zn (0.034-0.065) for 70 kg bw category and Cd (0.458-0.592); Hg (98.3-99.0); Ni (0.137-0.298); Pb (0.398-0.844); Zn (0.032-0.059) for 24 kg bw category. It is evident from the results that Hg is the major contributor to the overall non-carcinogenic risk values with more than 95% contribution in each sample for both adults and children's categories, showing high levels of contamination of the traditional herbal samples with Hg.

4. Conclusion

This study investigated the toxicity level of five samples of herbal medicines for humans. The results showed that many of the metals were within the World Health Organization's maximum permissible levels. However, Hg was found in the samples at high concentrations far above the recommended maximum limits by regulatory agencies. This contamination could come from the soil on which the medicinal plants were cultivated, processing methods or from the environment. The results of THQ for both adults and children categories indicate that only Hg would pose a non-carcinogenic health risk to the consumers; other metals were below the maximum limit of 1.0. High levels of HI in virtually all the samples showed that the combined effect of the heavy metals could pose cumulative health challenges when consumed for a long time. Moderate to high cancer risk could be developed from Pb whereas very high cancer risk could come from Cd by consuming the samples over a long period of time. High levels of Hg in this study are a serious health concern as it might be due to the onset of pollution. Therefore, regular monitoring and evaluation have to be carried out by concerned regulatory agencies to ensure the safety of the consumers.

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