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## RISK ASSESSMENT OF SOME HERBAL POWDERS AND HERBAL FORMULATIONS CONTAMINATED WITH HEAVY METALS

Meena Deswal<sup>1</sup>, Pawan Deswal<sup>2</sup> and J. S. Laura<sup>\*1</sup>

Department of Environmental Sciences<sup>1</sup>, Maharshi Dayanand University, Rohtak - 124001, Haryana, India.

Department of AYUSH<sup>2</sup>, Community Health Center, Village Dubaldhan, Jhajjar, Panchkula - 134109, Haryana, India.

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### Correspondence to Author:

**J. S. Laura**

Professor,  
Department of Environmental  
Sciences, Maharshi Dayanand  
University, Rohtak - 124001,  
Haryana, India.

**E-mail:** jslmdu@gmail.com

**ABSTRACT:** Ten herbal medicines, Four herb choornam (Trikatu, Hingwashtak, Triphala and sitopladi) and five herbal compounds - Kutajghan Vati, Gandhak Rasayan, Sarivadi Vati, Chanderprabha Vati, Shankh Vati were tested for levels of heavy metals (Lead, copper, cadmium, iron, chromium, manganese, nickel and zinc). Both herbal extracts and herbal formulations showed the presence of heavy metals. Concentrations were higher in the herbal formulations as compared to herbal extracts. The intake of the heavy metals has been calculated by taking into account the recommended daily dose of the given Ayurvedic medicines and their calculated average daily dose (ADD). The paper discusses the significance of these quantities regarding calculated daily limit given by various international food and drug administration agencies. Iron, zinc, and copper are classified as micro-nutrients, and these metals have been reported to be deficient in the diet. The prescribed medication of tested Ayurvedic medicines provides the required intake of these micronutrients. The study concludes that the tested Ayurvedic medicines are not only safe regarding heavy metal intake but apart from their therapeutic use they are also beneficial as they supply essential minerals most importantly iron which is usually deficient in the diet.

**INTRODUCTION:** Ayurvedic is a system of medicine of Indian origin. Ayurvedic medicines originated in India more than 2000 years ago and relied heavily on herbs and their formulations. It is known to be an upveda of Atharva Veda. WHO (world health organization) estimates that 80% of the world's population relies on these 'Alternative' plant-based medicines as their primary medical intervention<sup>1,2</sup>. Approximately 70 - 80% of India's population use Ayurveda through more than one-half million Ayurvedic practitioners working in 860 Ayurvedic hospitals and 22100 clinics<sup>3-5</sup>.

Ayurvedic medicines being prepared from herbs are usually considered safe and free from side effects. Considering the complexity of these drugs, their inherent biological variation it becomes necessary to evaluate their efficacy, safety and quality<sup>6</sup>. As per Indian Ayurvedic Product Market Forecast & Opportunities report, Global Ayurvedic Market in 2015 was accounted for \$3,428.0 million and is expected to reach \$9,791.0 million by 2022 growing at a compound annual growth rate of 16.0% during 2015-2022.

Due to heavy demand of herbal medicines natural resources of these herbs have depleted, so to meet the increasing demand, the medicinal herbs are cultivated on farms using standard agronomic practices which require input of fertilizers, pesticides, fungicides *etc.* to provide nutrition, protection from pests and diseases and to maintain high productive level<sup>7,8,9</sup>.

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It's well documented that chemical fertilizers and pesticides contain toxic substances which are taken up and accumulated in the various parts of the medicinal herbs. One such group of toxic substances is heavy metals. Ayurvedic formulations prepared using such herbs are likely to contain heavy metals taken up from the growth media<sup>10-16</sup>.

Heavy metal concentration in Ayurvedic medicines is of special concern in today's time, as the use of Ayurvedic medicines is increasing, and one of the most important reasons for heavy metal contamination is pollution from various sources. Also, air born heavy metals may be sources of foliar contamination, at least for lead<sup>17</sup> and cadmium<sup>18</sup>. Since contamination of herbs with heavy metals cannot be avoided as heavy metals are naturally present in the soil media as well as additional contamination from anthropogenic sources.

The Ayurvedic formulations contaminated with heavy metals can be said to be an unavoidable evil, as these heavy metals cannot be removed from the herbals and preparations. Since, 1978 at least 55 cases of heavy metal intoxication associated with Ayurvedic HMP (herbal medicinal preparations) in adults and children have been reported in the USA and abroad<sup>19</sup>. Hence, some international agencies

have come out with limits of daily dietary intake for the various heavy metals.

The US EPA (Environment protection agency, ASTDR (Agency for Toxic Substances and Disease Registry) has compiled priority list in 2001 called as "TOP 20 Hazardous Substances". The heavy metals arsenic, lead, mercury, and cadmium are ranked 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> respectively<sup>20</sup>. The various agencies like EPA, ATSDR, FDA (Food and drug agency) have made different criteria's. EPA has established a reference dose" (RfD) for inorganic arsenic, cadmium, and methylmercury. ATSDR within the U.S. Department of Health and Human Services also has established and maintains "minimal risk levels "(MLRs) for oral consumption of arsenic, cadmium, and methylmercury<sup>21</sup>. FDA has stated allowable level for Arsenic, Cadmium, Lead and Mercury in bottled drinking water. Some works on the estimation of heavy metals in herbal medicines are discussed in **Table 1**.

**Objective:** To determine the level of various heavy metals in four herbal powder and five herbal compounds formulations and to examine the results regarding toxicity levels in the prescribed dosage of test herbs, formulations and compare with the calculated daily limit and average daily dose (ADD) set by the international agencies.

**TABLE 1: ANALYSIS OF HEAVY METALS IN HERBS AND HERBAL MEDICINES**

Herbs	Analysis	Result	Place
Eight treasure herbal tea, Herbal tea, Xiyangshen root, Dangshen Root	Perkin Elmer Analyst 100 atomic absorption spectroscopy (AAS)	<ul style="list-style-type: none"> <li>Mn highest concentration (1.394-18.545 mg/L),</li> <li>Cd least (0.105-.314 mg/L),</li> <li>all other metals &lt;3 mg/L.</li> </ul>	Malaysia <sup>22</sup>
<i>Radix codonopsis</i> , Aloe, <i>Radix et Rhizoma rhei Palmati</i> , <i>Radix aconiti kusnezoffii</i> Preparata, <i>Radix hedysari</i>	AAS	<ul style="list-style-type: none"> <li>Maximum Pd in <i>Radix codonopsis</i> (83.12 µg/g).</li> <li>Maximum Cu in Aloe (74.3 µg/g).</li> <li>Maximum Cd in <i>Radix et Rhizoma Rhei Palmati</i> (1.318 µg/g).</li> <li>Maximum As in <i>Radix Aconiti Kusnezoffii</i> Preparata (15.84 µg/g).</li> </ul>	Beijing <sup>23</sup>
<i>Vernonia amygdaling</i> , <i>Ocimum viride</i> , <i>Paullinia pinnata</i> , <i>Azadiracta indica</i> , <i>Ocimum gratissium</i> , <i>Momordica charantia</i> , <i>Psidium guajava</i> , <i>Alchornea cordifolia</i> , <i>Cymopogon citrates</i> , <i>Taraxacum officinale</i> , <i>Carica Papaya</i> , <i>Gossypium herbaceum</i> , <i>Chromolena odorata</i> , <i>Cassia occidentalis</i> , <i>Garcinia kola</i>	VARIAN SPECTRA AA220 Zeeman Atomic Absorption Spectrometer	<ul style="list-style-type: none"> <li>Maximum Hg in <i>Radix hedysari</i> (9.11 µg/g).</li> <li>Maximum Fe in <i>Carica Papaya</i> (4.88 mg/kg).</li> <li>Maximum Zn in <i>Garcinia kola</i> (1.07 mg/kg).</li> <li>Maximum Cd in <i>Carica Papaya</i> (0.53 mg/kg).</li> <li>Maximum Pb in <i>Taraxacum officinale</i> (0.89 mg/kg).</li> </ul>	Ghana <sup>24</sup>
<i>Petroselinum crispum</i> , <i>Ocimum basilicum</i> , <i>Salvia offinalis</i> <i>Origanum vulgare</i> , <i>Mentha spicata</i> , <i>Thymus vulgaris</i> , <i>Matricaria chamomilla</i>	AA240FS series by Varian Australia AAS.	<ul style="list-style-type: none"> <li>Maximum Cd in <i>Ocimum basilicum</i> (0.13-1.11 mg/g).</li> <li>Maximum Pb in <i>Salvia offinalis</i> (12.66-21.76 mg/g).</li> <li>Maximum Cu in <i>Matricaria chamomilla</i> (6.12-12.99 mg/g).</li> <li>Maximum Zn in <i>Matricaria chamomilla</i> (25.23-</li> </ul>	Dubai, UAE <sup>25</sup>

<i>Basilici folium, Chamomillae folium, Mori folium, Plantaginis folium, Taraxaci herba, Menthae herba, Hyperici herna, Calendula flos, Foeniculi fructus, Anethi fructus</i>	AA-6300- Shimadzu double beam AAS.	38.93 mg/g).	Romania <sup>26</sup>
		• Maximum Fe in <i>Salvia officinalis</i> (204.15-799.31 mg/g)	
		• Maximum Pb in <i>Anethi fructus</i> (45.01 µg/g).	
		• Maximum Cd in <i>Menthae herba</i> (25.63 µg/g).	
		• Maximum Zn in <i>Calendula flos</i> (22.38 mg/kg).	
• Maximum Cu in <i>Calendula flos</i> (13.49 mg/kg).			

**MATERIALS AND METHODS:**

**Material:** The herbs and formulations were collected from reputed registered Ayurvedic stores.

The following samples were taken for heavy metal analysis **Table 2**.

**TABLE 2: HERBAL COMPOUND, COMPOSITION, SCIENTIFIC NAME AND MEDICINAL PROPERTIES**

S. no.	Name of formulation	Component	Botanical name	Use
1	Trikatu choornam	Sunthi Marich Pippali	<i>Zingiber officinale</i> <i>Piper nigrum</i> <i>Piper longum</i>	These herbs work in synergy to stimulate the digestive fire, or <i>agni</i> , allowing for more efficient digestion in the stomach while promoting proper bile flow, healthy detoxification and fat metabolism. The gentle heating action of this blend primes the digestive tract to digest food, absorb nutrients and efficiently remove wastes
2	Triphala Chooranam	Haritaki. Bahera Amla	<i>Terminalia chebula</i> <i>Terminalia bellirica</i> <i>Phyllanthus emblica</i>	Wards Off digestive problems, detoxifier Improves eyesight, improves blood circulation, boosts immunity, reduces inflammation, cures anemia, removes excess fat, aids weight loss, relieves bone and joint pain, regulates blood pressure, etc
3	Hingwashtak	Shwetjeera Marich Pippali Sunthi Kala jeera Ajwaian Heeng	<i>Cuminum cyminum</i> <i>Piper nigrum</i> <i>Piper longum</i> <i>Zingiber officinale</i> <i>Carum persicum</i> <i>Trachyspermum ammi</i> <i>Ferula assa-foetida</i>	Carminative and gastric stimulant, significant in flatulence, dyspepsia, colic, constipation, Ease in the detention of gas in the intestine, enkindles the appetite and enhances digestion. Stimulate healthy and unobstructed peristalsis, balances downward moving energies
4	Sitopladi choornam	Vanshlochan Pippali Ela Dalchini	<i>Bambusa arundinacea</i> <i>Piper longum</i> <i>Elettaria cardamomum</i> <i>Cinnamomum verum</i>	The remedy for seasonal coughs and colds, stimulate appetite, promote digestion, reduce sinus congestion and increase energy levels. (C.S.Ch.ch-8/103,104)
6	Kutajghan Vati	Kutaj Ativisha	<i>Wrightia antidysenterica</i> <i>Aconitum heterophyllum</i>	It is used in treating fever with diarrhea, dysentery, ulcerative colitis, mal absorption syndrome, S.Y.S.
7	Gandhak Rasayan	Twak Ela Patra Nagakeshara Guduchi Haritaki Amalaki Vibhitaki Shunti Bhringaraja Ardraka	<i>Cinnamomum zeylanicum</i> <i>Elettaria cardamomum</i> <i>Cinnamomum tamala</i> <i>Mesua ferrea</i> <i>Tinospora cordifolia</i> <i>Terminalia chebula</i> <i>Emblica officinalis</i> <i>Terminalia bellirica</i> <i>Zingiber officinalis</i> <i>Eclipta alba</i> <i>Zingiber officinalis</i>	It is used to treat chronic fever, skin diseases, diarrhoea, urinary tract disorders, pruritis, malabsorption syndrome, bleeding disorders, oligospermia
8	Sarivadi Vati	Sariva Mulethi Kooth Dalchini Choti Elachi Tejpatra Naagkesar Phoolpriyangu Nilotpa Giloy Laung Haritaki Amla Bahera Abhrak Bhasm,	<i>Hemidesmus indicus</i> <i>Glycyrrhiza glabra</i> <i>Saussurea costus</i> <i>Cinnamomum verum</i> <i>Elettaria cardamomum</i> <i>Cinnamomum tamala</i> <i>Mesua ferrea</i> <i>Callicarpa macrophylla</i> <i>Nymphaea stellata</i> <i>Tinospora cordifolia</i> <i>Syzygium aromaticum</i> <i>Terminalia chebula</i> <i>Phyllanthus emblica</i> <i>Terminalia bellirica</i> biotite (mica)	It is used in Ayurvedic treatment of ear problems such as Tinnitus, hearing loss, ear infection etc. It is also used to treat diabetes, bleeding diseases, chronic respiratory diseases, chronic fever, infertility treatment, epilepsy, alcoholism, and cardiac diseases. (B.R)

9 10	Shankh Vati (B.R Chanderprabha vati (Sidhyogsangrah)	Gunja	<i>Abrus precatorius</i>	Treatment of dyspepsia, low digestion power, anorexia, acid peptic diseases and emaciation
		Makoy	<i>Solanum nigrum</i>	
		Java	<i>Syzygium cumini</i>	
		Arjun	<i>Terminalia arjuna</i>	
		Bhringraj	<i>Eclipta prostrate</i>	
		Imli	<i>Tamarindus indica</i>	
		Yava kshara	<i>Hordeum vulgare</i>	
		Sendha Namak	Halite	
		Kala Namak	Rock salt	
		Samber	Sodium chloride (97.1%),	
		Namak	Total sulphide (0.06%), Sodium bicarbonate (0.049%)	
		Samudra	Sea salt	
		Namak		
		Shankh	Calcium carbonate	
		Nimbu	<i>Citrus limon</i>	
		Heeng	<i>Ferula assa-foetida</i>	
		Sunthi	<i>Zingiber officinale</i>	
		Marich	<i>Bryophyllum pinnatum</i>	
		Pippali	<i>Piper longum</i>	
		Kajjali	Sulfide of mercury	
		Nagarmotha	<i>Cyperus scariosus</i>	Antacid (mild effects), anti-inflammatory (potent anti-inflammatory for soft tissues and muscles), anti- arthritic (especially for spine and effects are visible in low backache), digestive Stimulant (mild effects – its effects are visible in patient with anorexia nervosa or mental stress due to over work load), emmenagogue (mild effects – but it harmonizes the menstrual flow by strengthening the female reproductive system), haematinic (increases hemoglobin levels – due to presence of Loha bhasma (iron Calx)), hematogenic (helps in formation of red blood cells), lowers bilirubin (mild effects – other liver medicines are also required), fat Burner (due to shilajit and Loha bhasma), anti-gout (it increases urinary excretion of uric acid), analgesic (in gout and osteoarthritis), muscle relaxant (its effects appear on uterine muscles during painful periods), anthelmintic (due to Vidanga), mild anti-hypertensive, it is indicated for urinary tract infestations (UTI), Madhumeha. <sup>4</sup>
		Chirayta	<i>Swertia</i>	
		Giloy	<i>Tinospora cordifolia</i>	
		Devdaru	<i>Cedrus deodara</i>	
		Haladi	<i>Curcuma longa</i>	
		Ativisha	<i>Aconitum heterophyllum</i>	
		Daruhaldi	<i>Berberis aristata</i>	
		Chitrakmool	<i>Plumbago zeylanica</i>	
		Dhaniya	<i>Coriandrum sativum</i>	
		Chavya	<i>Piper retrofractum</i>	
		Vidang	<i>Embelia ribes</i>	
		Gajpippal	<i>Piper chaba</i>	
		Trikatu	<i>Piper nigrum</i>	
		Swarnmakshik bhasm	<i>Piper longum</i>	
		Sajjikashar	<i>Zingiber officinale</i>	
		Yavakshar	Chalcopyrite is the copper containing mineral.	
		Sendha lavan	Crude carbonate of sulphate	
		Sambhar lavan	<i>Hordeum vulgare</i>	
		Choti elaichi	Halite	
		Kabab chini	Sodium chloride (97.1%),	
		Gokshur	Total sulphide (0.06%),	
		Shwetchandan	Sodium bicarbonate (0.049%)	
		Nisoth	<i>Elettaria cardamomum</i>	
		Dantimool	<i>Piper cubeba</i>	
		Dalchini	<i>Tribulus terrestris</i>	
		Vanshlochan	<i>Santalum ovatum</i>	
		Lauh bhasm	<i>Operculina turpethum</i>	
		Shilajatu	<i>Baliospermum montanum</i>	
		Giloy	<i>Cinnamomum verum</i>	
		Gugglu	<i>Bambusa arundinacea</i>	
		Kapurkachri	Oxide of iron.	
			<i>Asphaltum punjabianum</i>	
			<i>Tinospora cordifolia</i>	
			<i>Commiphora wightii</i>	
			<i>Hedychium Spicatum</i>	

**Estimation of Heavy Metals:** Samples were dried in a hot air oven at 60 °C for 4 h. Dried samples were ground, and 1 gram of sample was digested in an acid mixture of nitric acid and hydrochloric acid in ratio of 1:3 (Aquaregia). The digested samples were cooled and filtered through a glass fiber filter. The final volume made to 25 ml with distilled

water. The filtered samples were subjected to analysis for heavy metals using a double beam Atomic Absorption Spectrophotometer (Electronic Corporation of India Ltd., (ECIL), model AAS4141). Calibration curves of each metal were prepared by dilution of 1000 mg /L standard stock solution of the metals. The absorbance readings



obtained were then calculated using the equations generated from the curves for each metal.

**Risk Assessment:** Daily ingestion of heavy metal through medication was calculated according to equation 1.

$$C = A / B \dots\dots(1)$$

A= Concentration of heavy metal in sample ( $\mu\text{g}/\text{gm}$ ); B= Capsule/ tablet weight in gram; C= Concentration of heavy metal in Capsule/ tablet ( $\mu\text{g}$ ).

Daily ingestion of heavy metal = C  $\times$  Prescribed a number of capsules/ tablets per day.

Average daily dose (ADD) calculation is recommended by the joint FAO / WHO Expert

Committee on Food Additives<sup>27-29</sup> for the risk assessment of heavy metals in Ayurvedic medicines and is computed according to Eq. (2)

$$\text{ADD} = (\text{CH} \times \text{ID} \times \text{EF} \times \text{ED}) / (\text{BW} \times \text{AT}) \dots\dots(2)$$

Where ADD is average daily dose ( $\mu\text{g}/\text{kg}/\text{day}$ ), CH is the concentration of toxic metals ( $\mu\text{g}/\text{gm}$ ), ID is the ingestion dose (mg or gram/day), EF is the exposure frequency (taken as 60 days/year), ED is the exposure duration (48.35 Year), BW is the body weight (kg), and AT is the average lifespan, it has been taken as 68.35 years for both male and female of Indian origin<sup>30</sup>. The average weight was taken as 63.05 kg for male and 52.6 kg for female<sup>31</sup>. The CH value was based on the recommended daily dose of the Ayurvedic medicines.

**TABLE 3: CONCENTRATION OF HEAVY METALS IN THE AYURVEDIC MEDICINE SAMPLES**

S. no.	Name	Mean $\pm$ SD concentration ( $\mu\text{g}/\text{gm}$ )							
		Cu	Pb	Fe	Cr	Cd	Zn	Mn	Ni
1	Triphala Ch.	9.49 $\pm$ 0.02	3.25 $\pm$ 0.06	195.56 $\pm$ 0.01	BDL	0.99 $\pm$ 0.02	12.63 $\pm$ 0.08	8.98 $\pm$ 0.08	BDL
2	Hingwashtak Ch.	11.36 $\pm$ 0.05	2.99 $\pm$ 0.05	229.66 $\pm$ 0.06	BDL	0.56 $\pm$ 0.02	23.06 $\pm$ 0.05	6.96 $\pm$ 0.04	0.40 $\pm$ 0.04
3	Bahera Ch.	3.73 $\pm$ 0.04	3.12 $\pm$ 0.09	215.46 $\pm$ 0.04	BDL	0.98 $\pm$ 0.07	6.23 $\pm$ 0.03	23.14 $\pm$ 0.06	BDL
4	Sitopladi Ch.	12.16 $\pm$ 0.06	3.21 $\pm$ 0.04	455.33 $\pm$ 0.06	BDL	0.65 $\pm$ 0.04	17.00 $\pm$ 0.01	4.69 $\pm$ 0.07	1.40 $\pm$ 0.08
5	Kutajghan Vati	8.67 $\pm$ 0.01	9.78 $\pm$ 0.07	588.67 $\pm$ 0.05	BDL	1.15 $\pm$ 0.09	18.10 $\pm$ 0.04	12.86 $\pm$ 0.06	18.40 $\pm$ 0.06
6	Gandhak Rasayan	10.42 $\pm$ 0.08	9.48 $\pm$ 0.01	33.17 $\pm$ 0.04	BDL	1.56 $\pm$ 0.08	2.85 $\pm$ 0.06	6.24 $\pm$ 0.09	2.00 $\pm$ 0.01
7	Sarivadi Vati	13.00 $\pm$ 0.03	2.89 $\pm$ 0.02	695.50 $\pm$ 0.04	BDL	0.79 $\pm$ 0.04	50.36 $\pm$ 0.04	14.00 $\pm$ 0.04	40.64 $\pm$ 0.05
8	Shankh Vati	8.20 $\pm$ 0.05	4.99 $\pm$ 0.01	499.50 $\pm$ 0.00	BDL	1.95 $\pm$ 0.04	7.06 $\pm$ 0.08	67.63 $\pm$ 0.01	32.43 $\pm$ 0.01
9	Chanderprabha Vati	45.65 $\pm$ 0.04	5.47 $\pm$ 0.06	690.12 $\pm$ 0.05	12.97 $\pm$ 0.02	0.96 $\pm$ 0.00	24.83 $\pm$ 0.01	17.37 $\pm$ 0.00	30.40 $\pm$ 0.01

BDL: Below detectable limit.

**TABLE 4: HEAVY METALS CONCENTRATION IN THE RECOMMENDED DAILY DOSE**

S. no.	Name	Quantity in the daily dose ( $\mu\text{g}$ )							
		Cu	Pb	Fe	Cr	Cd	Zn	Mn	Ni
1*	Trikatu Ch.	64.1	17.3	609.9	BDL	4.9	103.0	31.7	43.8
2*	Triphala Ch.	56.9	19.5	1173.4	BDL	5.9	75.8	53.9	BDL
3*	Hingwashtak Ch.	68.2	17.9	1377.9	BDL	3.4	138.4	41.8	2.4
4*	Sitopladi Ch.	72.9	19.3	2731.9	BDL	3.9	102.0	28.1	8.4
5*	Kutajghan Vati	4.3	4.9	294.3	BDL	0.6	9.1	6.4	9.2
6**	Gandhak Rasayan	5.2	4.7	16.6	BDL	0.8	1.4	3.1	1.0
7**	Sarivadi Vati	6.5	1.5	347.8	BDL	0.4	25.2	7.0	20.3
8**	Shankh Vati	4.1	2.5	249.8	BDL	0.9	3.5	33.8	16.2
9**	Chanderprabha Vati	22.8	2.7	345.1	6.48	0.5	12.4	8.7	15.2

Recommended dose- \* 3g bid, \*\* 250 mg bid.

**TABLE 5: AVERAGE DAILY DOSE (ADD)  $\mu\text{g}/\text{kg}/\text{DAY}$  OF HEAVY METALS FOR INDIAN MALE**

S. no.	Name of medicine	Cu	Pb	Fe	Cr	Cd	Zn	Mn	Ni
1	Trikatu Ch.	42.9	11.6	408.6	BDL	3.3	69.0	21.2	29.4
2	Triphala Ch.	38.2	13.1	786.2	BDL	3.9	50.8	36.1	BDL
3	Hingwashtak Ch.	45.7	12.0	923.2	BDL	2.3	92.7	27.9	1.6
4	Sitopladi Ch.	48.9	12.9	1830.4	BDL	2.6	68.3	18.9	5.6
5	Kutajghan Vati	2.9	3.3	197.2	BDL	0.4	6.1	4.3	6.2
6	Gandhak Rasayan	3.5	3.2	11.1	BDL	0.5	1.0	2.1	0.7
7	Sarivadi Vati	4.4	1.0	232.9	BDL	0.3	16.8	4.7	13.6
8	Shankh Vati	2.7	1.7	167.3	BDL	0.7	2.4	22.7	10.9
9	Chanderprabha Vati	15.3	1.8	231.2	4.34	0.3	8.3	8.7	10.2

**TABLE 6: AVERAGE DAILY DOSE (ADD)  $\mu\text{g}/\text{kg}/\text{day}$ , OF HEAVY METALS FOR INDIAN FEMALE**

S. no.	Name of medicine	Cu	Pb	Fe	Cr	Cd	Zn	Mn	Ni
1	Trikatu Ch.	51.9	14.0	494.0	BDL	3.9	83.4	25.7	35.5
2	Triphala Ch.	46.1	14.0	950.4	BDL	4.0	61.4	43.6	BDL
3	Hingwashtak Ch.	55.2	14.5	1116.2	BDL	2.7	112.1	33.8	1.9
4	Sitopladi Ch.	59.1	14.0	2212.9	BDL	3.2	82.6	22.8	6.8
5	Kutajghan Vati	3.5	3.9	238.4	BDL	0.5	7.3	5.2	7.5
6	Gandhak Rasayan	4.2	3.8	13.4	BDL	0.6	1.2	2.5	0.8
7	Sarivadi Vati	5.3	1.2	281.7	BDL	0.3	20.4	5.7	16.5
8	Shankh Vati	3.3	2.0	202.3	BDL	0.8	2.9	27.4	13.1
9	Chanderprabha Vati	18.5	14.2	279.5	5.24	0.4	10.1	7.0	12.3

**TABLE 7: CURRENT QUANTITATIVE HEAVY METAL LIMITS OF U.S. AGENCIES**

Name	Agency/ Scope	Stated limit	Calculated daily limit (Adult)
Arsenic	FDA/ Bottled drinking water	Allowable level=10 $\mu\text{g}$ arsenic/liter	20 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/Drinking water	MCL =10 $\mu\text{g}$ arsenic/liter	20 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/IRIS	RfD (Chronic effect; noncancer) =0.3 $\mu\text{g}$ inorganic arsenic /kg body weight	21 $\mu\text{g}$ (Calculated at 70 Kg)
	ATSDR	MRL(chronic oral consumption) =0.3 $\mu\text{g}$ inorganic arsenic /kg body weight	21 $\mu\text{g}$ (Calculated at 70 Kg)
Cadmium	FDA/ Bottled drinking water	Allowable level=5 $\mu\text{g}$ cadmium/liter	10 $\mu\text{g}$ (Calculated at 2 liters/day)
	EPA/Drinking water	MCL = 5 $\mu\text{g}$ cadmium/liter	10 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/IRIS	RfD (Chronic effect ; noncancer) =1.0 $\mu\text{g}$ cadmium/kg body weight	70 $\mu\text{g}$ (Calculated at 70 Kg)
	ATSDR	MRL (chronic oral consumption) =0.2 $\mu\text{g}$ cadmium/kg bw	14 $\mu\text{g}$ (Calculated at 70 Kg)
Lead	FDA/ Bottled drinking water	Allowable level= 5 $\mu\text{g}$ lead/liter	10 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/Drinking water	Action level= 15 $\mu\text{g}$ / liter	30 $\mu\text{g}$ (calculated at 2 liters/day)
Mercury	FDA/ Bottled drinking water	Allowable level= 2 $\mu\text{g}$ mercury/liter	4 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/Drinking water	MCL = 2 $\mu\text{g}$ mercury/liter	4 $\mu\text{g}$ (calculated at 2 liters/day)
	EPA/IRIS	RfD (Chronic effect ; noncancer) = 0.1 $\mu\text{g}$ methyl mercury/kg body weight	7 $\mu\text{g}$ (Calculated at 70 Kg)
	ATSDR	MRL (chronic oral consumption) = 0.3 $\mu\text{g}$ methyl mercury/kg body weight	21 $\mu\text{g}$ (Calculated at 70 Kg)

FDA; Food and Drug Administration, EPA; Environmental Protection Agency, IRIS; Integrated risk information system; ATSDR; Agency for Toxic Substances and Diseases Registry. Source- AHPA., 2009

**TABLE 8: HEAVY METAL LIMITS FOR CANADA'S NATURAL HEALTH PRODUCTS<sup>32</sup>**

Metal	Stated limit	Calculated daily limit (Adult, 70 kg)
Arsenic	0.14 $\mu\text{g}$ "arsenic and its salts and derivatives"/ kg body weight	10 $\mu\text{g}$
Cadmium	0.09 $\mu\text{g}$ cadmium/ kg body weight	6 $\mu\text{g}$
Lead	0.29 $\mu\text{g}/\text{kg}$ body weight	20 $\mu\text{g}$
Mercury	0.29 $\mu\text{g}$ "mercury and its salts and derivatives"/ kg body weight"	20 $\mu\text{g}$

**TABLE 9: CLINICAL IMPLICATIONS OF NUTRITIONAL TRACE ELEMENTS<sup>33</sup>**

S. no.	Mineral	Recommended Daily Dose	Functions in body	Deficiency
1	Iron	Premenopausal:18mg/day Postmenopausal female and male: 8mg/day	Component of hemoglobin, metalloprotein, oxygen transport	Iron deficiency anemia Hemosiderosis Hemochromatosis
2	Zinc	Female: 8mg/day, Male: 11 mg/day	Protein synthesis, zinc finger protein, component of enzymes	Ageusia, Growth retardation, Dermatitis, Hypogonadism, Acrodermatitis enteropathica,
3	Copper	900 mg/day	Cellular respiration, collagen synthesis, component of enzymes, antioxidant	Copper deficiency, Nausea, vomiting Menke's kinky hair syndrome, Hypochromic anemia, Skeletal defects, Wilson's disease
4	Chromium	Female: 25 $\mu\text{g}/\text{day}$ , Male:35 $\mu\text{g}/\text{day}$	Glucose tolerance factor	Hyperglycemia, neuropathy, encephalopathy, Dermatitis, eczema, bronchogenic carcinoma
5	Manganese	Female:1.8 mg/day Male:2.3 mg/day	Component of metalloenzymes, Manganese superoxide dismutase	Hair and nail changes, impaired clotting factors Parkinsonism like features
6	Nickel	Less than 100 micrograms /day		
7	Lead	-	-	-
8	Cadmium	7 micrograms/kg body weight/week		

**RESULTS AND DISCUSSION:** Represented in **Table 3** are the concentrations of the various heavy metals in the tested Ayurvedic preparations. In all the samples the heavy metals have been detected in varying quantities. Presence of heavy metals in Ayurvedic preparations has been reported in earlier works as well<sup>34-40</sup>. Iron in the Ayurvedic preparations (Tablet) has been detected in large quantity as compared to the powder, among the Sarivadi vati, Chanderprabha vati, Kutajghan vati and shankh vati have the higher concentration of the heavy metal. The highest concentration of copper, zinc, and manganese were found in Chanderprabha vati, Sarivadi vati, and Shankh vati respectively.

In **Table 4** are presented the calculated values of the heavy metals in the capsules and tablet standard presentation of the products. **Table 7** gives the concentration of heavy metal intake in the prescribed daily dose of the herbal extracts and Ayurvedic preparations. **Table 5** and **Table 6** give the average daily dose of the studied Ayurvedic products for male and female respectively. The average daily dose represents the amount of the intake calculated for the whole lifespan of an individual, and its value is less than the daily intake calculated by the recommended dose<sup>41</sup>.

Also, the ADD of males was less than females. The daily intake of the heavy metals through the prescribed daily dose of these Ayurvedic medicines, as well as the calculated average daily dose, are compared with the Calculated Daily Limit in dietary intake given by the American and Canadian agencies as given in **Table 7** and **Table 8**, it is observed that the quantities ingested are within limits prescribed by these agencies for both males and females.

Hence, these Ayurvedic medicines can be considered to be safe. Moreover, some of the heavy metals such as Iron, zinc copper, manganese, chromium have been reported to be essential for good health **Table 9**. However, these metals have been reported to be deficient in the diet<sup>42</sup> and required to be made up through the use of supplements. However, the tested herbal medicines contain these nutrients and consumption of these medicines makes up for the deficiency of these minerals in the diet.

**CONCLUSION:** The tested Ayurvedic medicines are not only safe regarding heavy metal intake but apart from their therapeutic use they are also beneficial as they supply some of the essential minerals most importantly iron which is usually deficient in the diet. These minerals may also have a synergetic effect on the activity of these Ayurvedic medicines.

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