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Evaluation of toxic heavy metal content in marketed Ayurvedic decoctions using closed vessel microwave digestion in ICPMS

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The heavy metal toxicity of marketed Ayurvedic herbal formulations has been sporadically reported in the literature. Drakshadi (DK) and Gandharvahastadi (GK) decoctions are widely prescribed classical Ayurvedic herbal formulations. The potential adverse heavy metal toxicity due to consequent intake of DK and GK have been published in scientific papers or reported through pharmacovigilance. The objective of our investigation was to determine the presence of heavy metals in marketed DK and GK, with reference to the Ayurveda Pharmacopeia of India (API) standards. In this study, the concentration of four heavy metals, Arsenic (As), Cadmium (Cd), Lead (Pb), and Mercury (Hg) were investigated using Inductively Coupled Plasma- Mass Spectrometer (ICP-MS). These metals are not known to have any role in the pharmacological activity of these formulations. However, their presence beyond acceptable limits can have harmful consequences. Eighteen random samples each of DK and GK decoctions were collected from different pharmacy outlets, Kerala province, India. We tested 36 market samples of the above formulations for heavy metals, which were found to be within the limits prescribed by the Ayurvedic Pharmacopoeia of India. Our study suggests that heavy metal contamination of Ayurvedic formulations may not be widespread as suspected. However, continuous dynamic monitoring of Ayurvedic herbal formulations for heavy metal contamination is warranted considering the possibility of inadvertent contamination of raw drugs from environmental exposure.

Keywords: Ayurvedic herbal decoctions, Ayurvedic herbal formulations, Heavy metal contamination, Heavy metal toxicity, ICPMS

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The natural pharmaceutical industry relies heavily on medicinal plants as the primary source for health supplements[1]. The last few decades have witnessed the popularity of alternative medical approaches with increasing use of herbal supplements, natural products, as well as traditional Ayurvedic medicines, which are collectively termed complementary medicines[2]. However, herbal medicines including Ayurvedic medicines have raised concerns regarding their safety due to the possible presence of toxic heavy metals beyond permissible limits. Plants having medicinal and therapeutic action are brewed or blended to formulate herbal Ayurvedic medicines, which are codified in the ancient Ayurvedic textbooks. The heavy metal uptake by plants from the environment and ensuing accumulation along the food chain is a latent and potential threat to animals and human beings, if not closely monitored[3,4]. Ayurvedic medicinal formulations are also at risk of heavy metal contamination as raw materials are sourced from the natural environment.

Studies revealed that some of the Ayurvedic herbal formulations that have been sold in Boston-area stores (USA), showed the presence of heavy metals beyond the specified limits[5]. In recent years, sporadic incidences of heavy metal toxicity following the use of traditional Ayurvedic medicines have been reported[6-8]. *Riccinus communis* L., a major ingredient of GK (Table 1), has scavenging capacity for Pb and Cd. The plant proved the best source of phytoremediation in waste land to combat heavy metal toxicity from the soil[9]. Another study showed that *R. communis* L. and its associated rhizobacterium had phytoremediation potential for metals and organic pollutants present in distillery wastewater. Hence, *R. communis* L. have been using on a wide scale for the treatment of distillery wastewater pollution[10]. *Zingiber officianale*, widely used herb in both traditional and contemporary

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natural medicine, a main ingredient of GK (Table 1). Literature survey notified that lead and cadmium toxicity in *Z. officianale*[11,12]. Excess Pb can also affect the activity of antioxidant enzymes and the ROS (Reactive oxygen species) scavenging system[13] and thus reducing pharmacological activity of the plant.

Literature reports are available signifying the uptake of Pb and Cd by *Vitis vinifera*, resulted in Arbuscular Mycorrhizae (AM) on plant growth. At towered Pb addition, deplorable total soluble solids and enriched total acidity have been notified in the fruits[14]. Henceforth, *V. vinifera*, an unavoidable ingredient of DK (Table 2) has an inevitable capacity of Pb uptake. The *Glycyrrhiza glabra* harvesting from natural habitats, have been exposed to heavy metals contamination[15]. *Gmelina arborea*, an inevitable ingredient of DK (Table 2) has been applied for the elimination of Pb (II) and Cu (II) ions from aqueous solution[16]. K Chandrashekhar *et al.*[17] investigated the soil remediation contaminated by Pb toxicity. Pb hyperaccumulating herb, *Hemidesmus indicus* accumulate lead in shoots and roots. The phytoremediation study undoubtedly proved, *Hemidesmus indicus* has a curious ability to hoard Pb in roots and consequently displace to harvestable parts[17]. Another major component of DK (Table 2), *Cyperus rotundus* have been used for the bioremoval of heavy metals from polluted soil and aqueous solutions[18,19]. *Cyperus rotundus* had an enhanced absorption and accumulation of heavy metals from the polluted soil by lower rate by shoot than by root system (shoot: As 145 mg/g, Pb 512 mg/g, Cd102 mg/g, and Zn 110 mg/g, root: As 183 mg/g, Pb 82 mg/g, Cd 122 mg/g, and Zn 137 mg/g)[20]. Investigation reports has been spotted regarding the Pb accumulation of *Nelumbium speciosum*, *Vetiveria zizanoides,* and *Santalum album* ingredients of DK decoction (Table 2) at elevated levels[21-23]. The Literature survey suggests that, availing the herbs for formulating herbal Ayurvedic formulation without heavy metal analysis and purification, results heavy metal toxicity in the formulations.

Table 1 — Herbal ingredients list of GK decoction.

Sl. No.	Official name	Botanical name	Quantity (g)
1	Gandharavahastha	*Ricimus communis* Linn.	1
2	Chirabilva	*Holoptelia integrifolia* Planch	1
3	Chithraka	*Plumbago zeylanica* Linn (Sudhi)	1
4	Sunthi	*Zingiber officianale* Rosc	1
5	Harithaki	*Terminalia chebula* Retz	1
6	Punarnava	*Boerhavia diffusa* Linn	1
7	Duhsparsa	*Fagonia cretica* Linn	1
8	Arshoghni	*Curculigo orchioides* Gaertn	1

Table 2 — Herbal medicinal plants used as ingredients for the preparation of DK decoction

Sl. no.	Official Name	Botanical name	Quantity (g)
1	Draksha	*Vitis vinifera* Linn.	0.3125
2	Madhuka	*Glycyrrhiza glabra* Linn.	0.3125
3	Madhooka	*Madhuca indica* J. F Gmel	0.3125
4	Lodhra	*Symplocos racemosa* Roxb	0.3125
5	Kashmari	*Gmelina arborea* Linn.	0.3125
6	Sariva	*Hemidesmus indicus*	0.3125
7	Musta	*Cyprus rotundus* Linn.	0.3125
8	Amalaki	*Embilca officinalis* Gaertn	0.3125
9	Hribera	*Coleus vettiveroides* K C Jacob	0.3125
10	Padmakesara	*Nelumbo nucifera* Linn.	0.3125
11	Patmaka	*Prunus cerasoides* D. Don	0.3125
12	Mrinala	*Nelumbo nucifera* Gaertn	0.3125
13	Chandana	*Santalum album* Linn.	0.3125
14	Ushira	*Vetiveria zizanioides* (Linn) Nash	0.3125
15	Neelothpala	*Monochoria vaginalis* Prest	0.3125
16	Parushaka	*Phoenix pusills* Gaertn	0.3125

Even at very low concentrations, heavy metals are known to have very low renal excretion rates[24]. They are difficult to metabolize and are found to accrue in the soft tissues[3]. They stimulate adverse effects due to their interference in many known normal biochemical and metabolic processes[25]. Among the toxic heavy metals, Arsenic (As), Cadmium (Cd), Lead (Pb), and Mercury (Hg) are found to be non-essential even at trace levels. Presence of heavy metals beyond the safe limits can lead to dysfunction in the central nervous system, liver, lungs, heart, kidney, and brain. This can cause hypertension, abdominal pain, skin eruptions, intestinal ulcer as well as the development of various types of cancers[26].

Although Ayurvedic medicines have health benefits, the sporadic reporting of heavy metal toxicity associated with the use of these medicines is a cause of major concern. According to Ayurveda pharmacopeia of India the permissible concentration limits of Arsenic (As), Cadmium (Cd), Mercury (Hg), and Lead (Pb) are 3 μg/g, 0.3 μg/g, 1 μg/g, and 10 μg/g respectively[27] (Table 3). Likewise, several other countries have issued guidelines for permissible heavy metal concentration in Herbal dietary supplements[28]. The data available on the presence of heavy metals in Ayurvedic formulations marketed in India are scanty[29].

The objective of our study was to evaluate heavy metal concentrations of As, Cd, Pb, and Hg in *Drakshadi* (DK) and *Gandharvahastadi* (GK) decoctions and whether they confirm to limits set by API[27]. The possibility of the presence of heavy metals in these formulations has been reported in a recent publication[30] and through pharmacovigilance program. DK formulation is indicated for management of anaemia, jaundice, and diseases caused due to imbalance of pitta (bile) as well as fever. DK has been prescribed as a liver tonic and for relieving tiredness. DK decoction, a herbal preparation made out of 16 herbal ingredients[31] (Table 2) has also been used for treating nasal bleeding, burning sensation, excessive thirst, and schizophrenia[32]. On the other hand, GK decoction has been reported to be significantly effective in reducing the total cholesterol, LDL, and triglyceride levels. GK decoction consists of 8 herbal ingredients[31] (Table 1) that have therapeutic effects in reducing systolic and diastolic blood pressure[33].

Methodology

In this study, we have collected 18 random samples of each decoction (a total of 36 samples) from different manufactures marketed within the Kerala province. The heavy metal content of these formulations was evaluated by ICP-MS (Inductively Coupled Plasma-Mass Spectrometer) and cross verified with the permissible limit mentioned in the API (Ayurveda Pharmacopeia of India).

Reagents

All reagents and chemicals used were of analytical grade quality. De-ionized water was obtained from Sartorius Arium® mini water system (sartorius), trace metal grade nitric acid (HNO_3, Fisher chemicals), trace metal grade hydrochloric acid (HCl, Fischer chemicals), Suprapur hydrogen peroxide (H_2O_2, Merck) was used for digesting samples. Stock standard solutions for Arsenic, Cadmium, Lead and Mercury containing 100 mg/L procured from Merck chemicals, USA. The certified reference materials (CRM) were purchased from the National Institute of Standard Technology (NIST) and used for the standardization and validation of the method.

Table 3 — Permitted values of heavy metals (As, Cd, Hg & Pb) recommended by API (Ayurveda Pharmacopoeia of India). NMT= Not More Than

Sl. no	Heavy metal	API limits (µg/g)
1	Arsenic (As)	NMT 3.0
2	Cadmium (Pb)	NMT 0.3
3	Mercury (Hg)	NMT 1.0
4	Lead (Pb)	NMT 10.0

Sample preparation

100 mL bottled GK and DK decoctions from selected manufacturers were purchased from licensed shops, Kerala province, India. The collected samples had proper labels which mentioned the type of preparations and ingredients. Each 5 mL of GK decoction was prepared from 8 herbal ingredients (Table 1) and each 5 mL of DK decoction was prepared out of 16 herbal ingredients (Table 2).

The 36 collected samples are carefully stored in a refrigerator. Laboratory wares used for this analysis were soaked in 2M HNO_3 for 36 h. Rinsed several times with distilled water and deionized water to prevent metal contamination of the samples. About 0.2-0.5 g of sample is taken in a clean MDS (Microwave Digestive System) container. 5 mL of Con. HNO_3 (Trace metal grade) was added followed by 0.5 mL of Con. HCl (trace metal grade). 1 mL of H_2O_2 (Suprapur) was added and kept the tube for pre-digestion in a boiling water bath for about 15 min. A blank was kept without adding the sample to MDS container (Fig. 1).

The closed vessel Microwave Digestive system (Anton Paar, Austria) was used to digest the samples. Sealed MDS containers were kept inside the digestive system and heated according to the digestion program (Microwave power – 850W); ramp time, 20 min; temperature, 185°C; hold time, 20 min, and cooling time 20 min (Fig. 1). After completing digestion, the

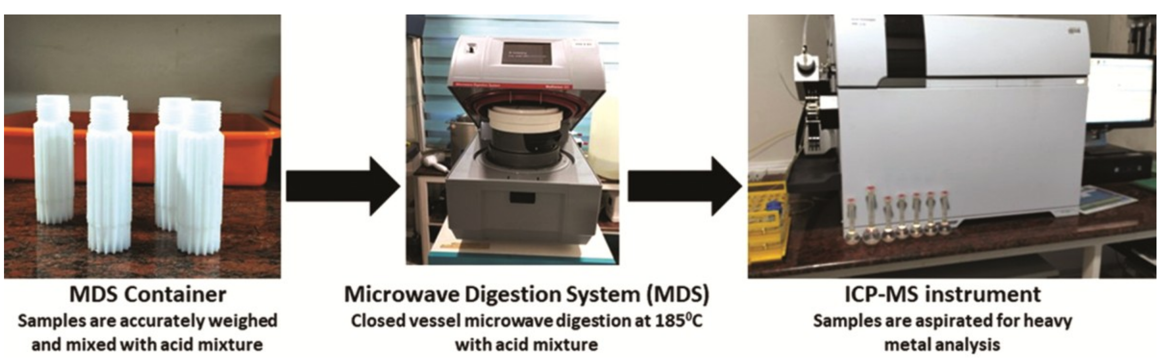

Fig. 1 — Brief experimental setup illustration of closed vessel microwave digestion and ICPMS instrument analysis

samples were cooled to room temperature and quantitatively transferred to a clean 50 mL volumetric flask and made up to 50 mL with deionized water.

1 µg/mL stock standard solution of As, Cd, Pb, and Hg was prepared and labelled. Six working standard solutions (0.5-250 µg/mL) has been prepared and used for plotting linear calibration curve for each heavy metal. 0.5% of trace metal grade Con.HNO_3 has been used for preparing 6 working standards. The method detection limit (MDL) or Limit of quantification (LOQ) has been set to 0.05 µg/mL. The concentration of heavy metals in each sample was calculated from standard calibration curves (Fig. 2).

To assess the concentration of heavy metals (As, Cd, Pb, and Hg) the decoction samples were aspirated to ICP-MS (Agilent 7800, USA) (Fig. 1). The ICP-MS instrument was adjusted to optimized conditions for better analytical results. The nebulizer gas flow is 0.9 L/min, Radiofrequency (RF) 1200W, lens voltage 1.5V, cool gas 12.5 L/min, and auxiliary gas 0.75 L/m. The method was previously standardized and validated using certified reference material (CRM) purchased from the National Institute of Standard Technology (NIST).

Statistical analysis has also been conducted using Single factor ANOVA with significant difference at $p<0.05$ using MS office excel 2019 professional software.

Results

Presence of the four heavy metals in 18 samples of DK decoction was found to be within the permissible limits prescribed by API. Each sample has been prepared and aspirated to ICPMS and repeated the procedure for another two times. The mean value of the result was taken and illustrated in Table 4. The statistical study has been performed, standard deviation and ANOVA for each metal, illustrated in the Table 4. The method detection limit has been set to 0.05 µg/g, hence any value below 0.05 µg/g portrayed as below detection limit (BDL). Heavy metal content of lead ranged from 0.11-0.51 µg/g (p-

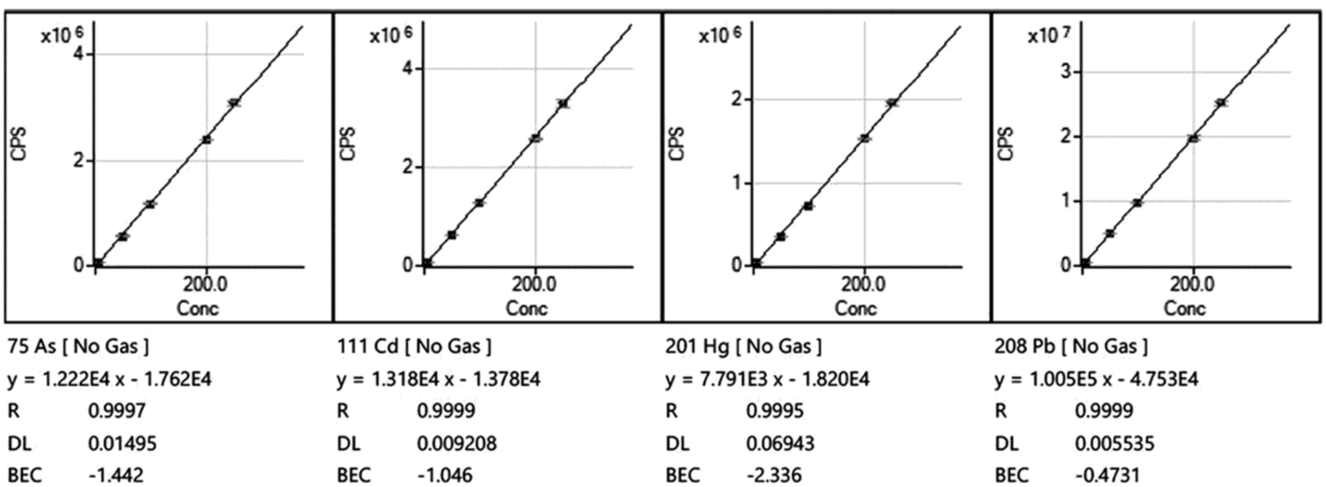

Fig. 2 — The external calibration curve obtained from the ICPMS instrument for As, Cd, Hg & Pb

Table 4 — ICPMS analysis results of DK decoction collected from the local markets of Kerala province. BDL- Below detection limit

Sample ID	DK01	DK02	DK03	DK04	DK05	DK06	DK07	DK08	DK09	DK10	DK11	DK12	DK13	DK14	DK15	DK16	DK17	DK18
Arsenic (As) [mg/kg]	0.19	0.19	0.24	0.26	0.13	0.15	0.23	0.23	0.16	0.42	0.43	0.43	0.31	0.31	0.27	0.41	0.09	0.07
Standard deviation	0.006	0.010	0.006	0.010	0.006	0.006	0.010	0.006	0.006	0.000	0.006	0.010	0.006	0.020	0.010	0.006	0.010	0.006
p-value	1.7444E-17																	
Cadmium (Cd) [mg/kg]	0.08	0.09	0.07	0.09	0.07	0.08	0.08	0.09	0.08	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL	Not detected
Standard deviation	0.010	0.006	0.006	0.010	0.010	0.000	0.010	0.006	0.006	-	-	-	-	-	-	-	-	-
p-value	4.17487E-09																	
Mercury (Hg) [mg/kg]	0.1	0.11	0.09	0.11	0.93	0.11	0.99	0.12	0.11	0.58	0.67	0.19	0.64	0.7	0.64	0.98	BDL	BDL
Standard deviation	0.006	0.006	0.010	0.000	0.006	0.010	0.025	0.006	0.000	0.006	0.006	0.010	0.010	0.010	0.000	0.030	-	-
p-value	7.57554E-27																	
Lead (Pb) [mg/kg]	0.42	0.46	0.39	0.46	0.39	0.51	0.45	0.47	0.45	0.25	0.23	0.25	0.18	0.19	0.17	0.25	0.41	0.42
Standard deviation	0.010	0.010	0.006	0.006	0.006	0.006	0.010	0.006	0.006	0.010	0.010	0.010	0.010	0.006	0.006	0.000	0.010	0.006
p-value	1.03143E-19																	

value <<0.05), that of mercury from BDL (below detection limit) – 0.99 µg/g (p-value <<0.05), that of cadmium from ND (Not detected)- 0.09 µg/g (p-value <<0.05) and that of Arsenic from 0.07-0.43 µg/g (p-value <0.05). The analysis indicates that DK07 and DK16 have the highest concentration of Hg content 0.99 µg/g and 0.98 µg/g (p-value <<0.05) respectively. As per the limit regulated by API (Table 3) the concentration of mercury should not be more than 1 µg/g. hence, the concentration of Hg in both DK07 and DK16 was on the upper limit. The acceptable recovery rate of metal concentration using ICPMS analysis ranges between 80-120%[34]. Moreover, 20% error chances are acceptable to the measured values obtained from the instrument. The permissible limit of mercury 1 µg/g, on incorporating 20% error chances the limit values will be revised to 1±0.2 µg/g. The addition of standard deviation to the observed value of DK07 (0.99±0.025) to DK16 (0.98±0.03), the limit values will be changed to 1.02±0.2 µg/g and 1.01±0.2 µg/g (±20% error) respectively. The data exhibit chances for contamination of mercury in DK07 and DK16 however it stands inconclusive.

The maximum concentration obtained for Cd was found to be 0.09 µg/g (p-value <<0.05) for three samples (DK02, DK04, & DK08), which is negligible compared to the limit prescribed by the API (Table 3). With respect to lead, DK06 has the highest concentration of 0.51 µg/g (p-value <<0.05) which is trivial compared to the API limit of 10 µg/g. The maximum concentration of Arsenic was 0.43 µg/g (p-value <<0.05) in DK11 and DK12 which is negligible compared to API limit of 3 µg/g.

The results of analysis of 18 samples of GK have been tabulated in Table 5. The statistical data including standard deviation and ANOVA for each metal have been depicted in the Table 5. The data revealed that concentration of lead ranged between 0.17 - 9.83 µg/g (p-value <<0.05), that of mercury between 0.1-0.73 µg/g (p-value <<0.05), that of cadmium between BDL (below detection limit)- 0.29 µg/g and that of arsenic between 0.14-0.51 µg/g (p-value <<0.05). GK13 sample revealed lead concentration of 9.83 (p-value <<0.05) µg/g on the upper side of the 10 µg/g limit permitted by API. The maximum concentration for arsenic was 0.51 µg/g (p-value <<0.05) in the sample GK14. The highest concentration of cadmium was seen in GK01 with the value 0.29 µg/g (p-value <<0.05), which is on the upper side of the 0.3 µg/g limit prescribed by API (Table 3).

The statistical data analyses indicate that the concentration of heavy metals in the DK and GK differs significantly depending on the manufacturers and the batches of samples taken for analysis (p-value <<0.05). Further, the data confirms that the content of As, Cd, Pb and Hg approximated the limits set by API (Table 3) after the addition of the acceptable 20% error chances of ICPMS instrument.

Discussion

Quantification of trace amounts of heavy metals in Ayurvedic herbal formulations using ICP-MS enables a rapid analysis with good precision and accuracy. In the class of Herbo-mineral formulations in Ayurveda, the heavy metals are added intentionally after a process of "purification"[35]. The safety of such formulations is debated and inconclusive. Nevertheless, preliminary studies indicate that such Herbo-mineral preparations may be safe if prepared according to the protocols laid out in the Ayurvedic tradition[36]. In this paper, our focus is on accidental contamination of herbal formulations with heavy metals, which are not processed for

Table 5 — ICPMS analysis results of GK decoction collected from the local markets of Kerala province. BDL- Below detection limit

Sample ID	GK01	GK02	GK03	GK04	GK05	GK06	GK07	GK08	GK09	GK10	GK11	GK12	GK13	GK14	GK15	GK16	GK17	GK18
Arsenic (As) [µg/g]	0.42	0.39	0.38	0.34	0.34	0.41	0.43	0.18	0.28	0.46	0.17	0.14	0.17	0.51	0.43	0.31	0.32	0.28
Standard deviation	0.310	0.360	0.360	0.343	0.029	8.408	0.150	0.160	0.140	0.150	0.010	6.667	0.630	0.630	0.640	0.633	0.006	0.912
p-value									3.33099E-15									
Cadmium (Cd) [µg/g]	0.29	0.29	0.25	0.15	0.23	0.27	0.27	0.08	0.09	0.27	0.08	0.08	0.08	BDL	BDL	BDL	BDL	BDL
Standard deviation	0.260	0.280	0.300	0.280	0.020	7.143	0.090	0.090	0.080	0.087	0.006	6.662	0.130	-	-	-	-	-
p-value									4.55674E-17									
Mercury (Hg) [µg/g]	0.71	0.73	0.65	0.63	0.58	0.68	0.68	0.18	0.14	0.65	0.10	0.11	0.11	0.73	0.66	0.15	0.11	0.65
Standard deviation	0.500	0.510	0.510	0.507	0.006	1.140	0.030	0.020	0.040	BDL	0.010	0.000	0.740	0.720	0.730	0.730	0.010	1.370
p-value									2.83041E-24									
Lead (Pb) [µg/g]	0.79	1.02	0.65	0.66	0.67	0.75	0.73	0.42	0.45	0.68	0.52	0.45	9.83	0.35	0.24	0.18	0.19	0.17
Standard deviation	0.020	0.010	0.006	0.006	0.010	0.000	0.006	0.006	0.006	0.010	0.006	0.006	0.006	0.010	0.006	0.006	0.010	0.000
p-value									1.8274E-43									

"purification" as per Ayurvedic principles. There is no dispute that such contamination can be harmful if heavy metals are present in higher unacceptable concentrations. Medicinal plants tend to assimilate heavy metals when they are grown in contaminated soils[37]. The wastewater irrigation aggravates the uptake of heavy metals in several aromatic plants although low levels of toxic elements were noticed in the volatile oils of these plants[38]. During the processing and preparation of ayurvedic products, cross-contamination of heavy metals may happen[39,40]. The processing of herbal plants for producing herbal medicines can impact the redistribution of heavy metals. It has been noticed that boiling the plants in water extracted a greater concentration of metals than immersing in hot water, indicating that the heavy metal contamination of the end-product can be managed by the extraction process[41].

In the two formulations that we studied, we found that in 14 batches, cadmium were below detectable levels (less than 0.05 µg/g) and in 1 batch (DK13) cadmium was not-detectable (less than 1 ng/kg). Similarly, mercury was observed to be below detectable level for 2 batches (DK17 and DK18). In all other batches, the four metals were detected but remained within prescribed limits[27]. In two batches of DK, mercury was found to be on the upper limit of the recommendation. We observed that in one batch of GK, lead was at the upper limit of recommendation. In one batch of GK, cadmium was on the upper side of the prescribed limit. Such variations across batches of the same formulation point towards the need for continuous batch by batch assessment of Ayurvedic formulations for presence of heavy metals before they are made available in the market.

The Food and Agricultural Organization of the United Nations and World Health Organization (FAO/WHO) limits the heavy metal contaminants in dietary supplements based on Permitted Daily Exposure (PDE). PDE is derived from each heavy metal contaminant (µg/day) from air, food, and water, calculated from Provisional Tolerable Weekly Intake (PTWI) recommended by FAO/WHO (U.S. Food and Drug Administration). Current good manufacturing practice in manufacturing, packaging, labeling, and holding operations for dietary supplements[42]. The PDE (µg/day) of Arsenic (As), Cadmium (Cd), Lead (Pb), and Mercury (Hg) is shown in Table 6. The finished dietary supplement formulation can be used in any proportions if they meet the limits given for individual components limit (ICL) which has also been illustrated in Table 6. However, finished dietary supplement dosage forms should not exceed 10 g/day if the ICL values are greater than the values described in Table 6.

Table 6 — Permitted daily exposure (PDE) and Individual Components limit (ICL) recommended by FAO/WHO for Arsenic, Cadmium, Lead and Mercury.

Sl. no.	Heavy metals	PDE (µg/day)	ICL (µg/g)
1	Arsenic (Inorganic)	15	1.5
2	Cadmium	5	0.5
3	Lead	5	0.5
4	Mercury (Total)	15	1.5

Table 7 — The limit of heavy metal contaminants recommended by FSSAI in Food not specified category for Arsenic, Cadmium, Lead & Mercury

Sl. no.	Heavy metal	Specification (µg/g)
1	Arsenic (Inorganic)	1.1
2	Cadmium	1.5
3	Lead	2.5
4	Mercury (Total)	1

The Food Safety and Standards of India (FSSAI) described the limits of heavy metal contaminants in their appropriate monograph[43]. The heavy metals limit for herbal Ayurvedic dietary supplements are not specified in FSSAI regulations, hence can be included under the category "Foods not specified". The heavy metal limits of foods not specified is tabulated in Table 7.

Herbal Ayurvedic medicines do not have any separate regulations specified in FAO/WHO or FSSAI. Inclusion of herbal Ayurvedic medicines as an independent category based on robust risk assessment in FAO/WHO guidelines is warranted. The prescribed limits for heavy metals in Ayurveda formulations may need revision based on different dosage forms of Ayurvedic medicines. The limits prescribed by API for heavy metals may not comply with international guidelines for dietary supplements issued by agencies like FDA. This can be an impediment in global acceptance of Ayurvedic formulations.

Conclusion

Our study revealed that heavy metal content in random samples of DK and GK collected from various pharmacies has fluctuating concentration of heavy metals. However, the obtained results reveal that heavy metal concentrations varied widely depending on manufacturer and also across batches. This inconsistency can be due to environmental and agronomic conditions, varied exposure to pollution, cultivation of plants in contaminated soil, inadequate storage conditions, and sourcing of poor-quality herbs for preparation of Ayurvedic formulations. The level of toxic metals can be influenced by the differences in the geographical region, genetics, and composition of the soil. This calls for continuous batch-to-batch monitoring of Ayurvedic formulations and certification of safety with respect to heavy metals before marketing the medicines.

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Conflict of Interest

Authors do not have any competing or conflict of interest.

Author Contributions

NG & MMG facilitated the procurement of resources and formal analysis, SNS & SK aided the procurement of resources. RP contributed to the Conceptualization, Writing - Review & Editing, Supervision, and DM contributed to the Conceptualization, Methodology, Formal analysis, Investigation, Resources & Writing -Original Draft.

Data Availability

The article itself presents the analytical data that substantiates the outcomes of our study. Further data can be obtained from the ACARA Research Laboratory, Amrita School of Ayurveda, upon a reasonable request. Restrictions have been imposed on the accessibility of the data used in the current study, making it unavailable to the public. Nevertheless, the data can be obtained from the authors upon a reasonable request and with the consent of ACARA Research Laboratory, Amrita School of Ayurveda.

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