Quantitative Estimation of Lead in Marketed Ayurvedic Formulations by Atomic Absorption Spectrophotometry

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Abstract

Ayurvedic herbal formulations have been used in India since a long time. These are prepared by single or by a mixture of crude drugs meant to be dispensed as such. The safety and quality of herbal medicines has become increasingly important for health authorities, scientific community and the public alike. The presence of certain trace-elements and heavy metals, like lead has a great significance in these medicines, affecting health of the consumers. Lead is a soft, malleable heavy metal used in a variety of consumer products. It is a potent neurotoxin which is particularly harmful to children. It disrupts the nervous connections, hindering cognitive development. Lead toxicity damages the kidneys, liver and other organs. Various case studies have been done, reporting that some Ayurvedic formulations contained lead content up to 2%, which is in very high concentration as compared to the maximum tolerable limit of only 10 parts per million (ppm), according to WHO and AYUSH The study was aimed to determining 19 physico-chemical parameters and the evaluation of lead content, in different catagories of Ayurvedic preparations of three major herbal manufacturers: Dabur, Unjha, Divya. Estimation of lead was done by flame atomic absorption spectrophotometer. The parameters of about 33formulations of different categories were evaluated for the standards given by Ayurvedic Pharmacopeia, Indian Pharmacopeia, AYUSH and WHO. It was concluded that almost all the formulations complied with the standard parameters given by the above mentioned reference books. The major herbal manufacturers are aware of the standardization of their preparations.

Keywords: Ayurveda, herbal medicines, lead toxicity, atomic absorption spectrophotometer

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1. Introduction

Traditional systems of medicine have been used throughout the world for centuries, particularly in their country of origin. Certain ancient system of medicine, especially Ayurveda - the holistic system of medicine from India, is still used extensively [1]. Ayurvedic medicines are gaining popularity as complementary treatment with modern system of medicine. Ayurvedic medicines are used to treat a wide spectrum of diseases from headaches to cancer [2]. Formulations and dosage forms have great importance in Ayurveda. Ayurvedic formulations are generally multicomponent mixtures of plant and animal derived products, minerals and metals [3].

Metallic elements are plant constituents with biological activity. These are essential or toxic agents in metabolism [4]. Herbal medicines are likely to be contaminated with heavy metals. Some heavy metals may be essential for the human body in trace amounts. However, they may be toxic if present in a higher concentration. They have ability to bio-accumulate and disrupt functions of vital organs and glands in the human body such as brain, kidney and liver [5]. An accurate monitoring of their concentration is required. Population gets the organic pollutants and heavy metals by ingestion of contaminated or polluted food and water. The gravity of toxic effect depends on nature, concentration, body resistance and presence of other contaminants. The concentration of this element in food products is varied, depending on their origin, storage conditions and processing technologies [6].

Considering the complexity of these drugs and their inherent biological variation, it becomes necessary to evaluate their efficacy, safety and quality [4]. Therefore, for the quality assessment of herbal formulations, standardization is needed based on their physical, chemical or phytochemical properties or estimating the concentrations of toxic metals qualitatively or quantitatively.

CDC (Centre for Disease Control and prevention), a Morbidity and Mortality WeeklyReport (MMWR), reported six cases of lead poisoning investigated by *Department of Health and Mental Hygiene (DOHMH), the New York City, during 2011–2012,*which were associated with the Ayurvedic medications manufactured in India. These cases from case 1 to 6 were as follows [7]:

Case 1: In January 2011, a woman born in India, aged 30 years, was prescribed an Ayurvedic medication *Pregnita,* for pregnancy-related nausea and vomiting. On testing the formulation Pregnita, 1.2% lead content was found.

Case 2: In May 2011, a woman born in Colombia, aged 36 years, used two Ayurvedic medications *Vatvidhwansan Ras and Kankayan Bati (Gulma),* manufactured in India for skin problems. Vatvidhwansan Ras contained 2% lead, 1.5% mercury and 130 ppm arsenic. Kankayan Bati (Gulma) contained 12 ppm lead, 35 ppm mercury, and 9.5 ppm arsenic.

Case 3: In June 2011, a woman born in India, aged 24 years, ingested two tablets of the Ayurvedic prenatal medication *Garbhapal Ras* daily to "keep her pregnancy and fetus healthy." Garbhapal Ras was found to contain 2.2% lead, 1.9% mercury and 410 ppm arsenic.

Case 4: In August 2011, a woman born in India, aged 35 years, used Ayurvedic medications *Ovarin* to promote fertility. It was found to contain as much as 1.2% lead, 1,000 ppm arsenic, and 1.8% mercury.

Case 5: In January 2012, a woman born in India, began using five different Ayurvedic medications to improve fertility and one to improve skin complexion Elevated levels of lead, mercury, or arsenic were found in five of the six medications. *Ovarin* was found to contain 2.4% lead, 7% mercury, and 100 ppm arsenic. *Garbha Dharak Yog* was found to contain 10% mercury, 140 ppm arsenic, and 110 ppm lead. *Laxmana Louh* was found to contain 180 ppm lead, 120 ppm mercury, and 12 ppm arsenic. *Garbha Chintamani Ras (Vrihat) (Swarna Yukt)* was found to contain 5.2% arsenic and 120 ppm lead. *Pigmento* was found to contain 2.9% mercury, 27 ppm arsenic, and 7.3 ppm lead.

Case 6: In May 2012, a woman born in India, aged 35 years, had begun using six medications to increase her chances of "having a male baby." One of the medications, *Garbhapal Ras,* was found to contain 1.5% lead, 0.44% mercury, and 81 ppm arsenic.

Case 7: A case report of a 58-year-old woman from India residing in the U.S.A., presented by Gunturu *et. al.* in Journal of Hematology & Oncology 2011 entitled Ayurvedic herbal medicine and lead poisoning. She presented with abdominal pain, anemia, liver function abnormalities, and an elevated blood lead level. The patient was found to have been taking the Ayurvedic medicine *Jambrulin.* The pill tested was found to contain approximately 21.5 mg of lead [2].

*Case 8:*An another case report of a 37 years old western European man was mentioned by B M Spriewald in SHORT REPORT in journal *Occup Environ Med* 1999, under the title Lead induced anemia due to traditional Indian medicine: a case report. Man had severe anemia after ingestion of several Ayurvedic drugs, obtained during a trip to India. Laboratory findings showed high blood lead concentrations, an increased urinary lead concentration, and also, slightly increased urinary concentrations of arsenic and silver were found [8].

1.1 LEAD

The metallic element lead has been known since the earliest historic time and it is a soft metal of bluish gray color. Lead is a freebly basignic metal, and the element itself in its behavior towards air and acids, resembles such heavy metals as copper and mercury. The chief ore of lead is galene, PbS which is associated with zinc chloride, iron pyrites and traces of silver. The other minerals containing lead are anglesite $PbSO_4$, cerrusite $PbCO_3$, Chlorophosphite $PbSO_4$ from solution of lead salts [9].

1.1.1 Physical and Chemical Properties of Lead

Symbol	:	Pb
Atomic number		82
Relative atomic mass	:	207.19
Electronic configuration		2, 8, 18, 32, 18, 4
Valency	:	2 & 4
Melting point		327.5°C
Boiling point	:	1740°C
Specific gravity	:	11.34

1.1.2 Effects on humans

In humans, lead can result in a wide range of biological effects depending upon the level and duration of exposure. It affects the subcellular level, as well as the overall functioning of the body. It ranges from inhibition of enzymes to the production of marked morphological changes and death. Such changes occur over a broad range of doses, the developing human generally being more sensitive than the adult.

Lead has been shown to have effects on many biochemical processes; in particular, effects on haem synthesis have been studied extensively in both adults and children. Increased levels of serum erythrocyte protoporphyrin and increased urinary excretion of coproporphyrin and delta-aminolaevulinic acid are observed when PbB (blood lead) concentrations are elevated. Inhibition of the enzymes delta-aminolaevulinic acid dehydratase and dihydrobiopterin reductase are observed at lower levels.

The effects of lead on the haemopoietic system result in decreased haemoglobin synthesis, and anaemia. For neurological, metabolic and behavioral reasons, children are more vulnerable to the effects of lead than adults. Lead has been shown to be associated with impaired neurobehavioral functioning in children.

Impairment of psychological and neurobehavioral functions occur after long-term lead exposure of workers. Peripheral neuropathy has long been known to be caused by long-term high-level lead exposure at the workplace. Slowing of nerve conduction velocity occurs at lower levels. These effects have often been found to be reversible after cessation of exposure depending on the age and duration of exposure.

The effect of lead on the heart is indirect and occurs via the autonomic nervous system; it has no direct effect on the myocardium. Lead is known to cause proximal renal tubular damage, characterized by generalized aminoaciduria, hypophosphataemia with relative hyperphosphaturia and glycosuria accompanied by nuclear inclusion bodies, mitochondrial changes and cytomegaly of the proximal tubular epithelial cells. The reproductive effects of lead in the male are limited to sperm morphology and count. In the female, some adverse pregnancy outcomes attributes due to lead [10].

2. Materials and methods

11 different formulations of three brands i.e. total 33 formulations of 6 different categories were purchased. The category of formulations with brand name, manufacturer, manufacturing date (Mfg. Dt.), expiry date (Exp. Dt.), and uses were recorded in **table 1 and table 2**. All the reagents used were of analytical grade.

Table 1: Details of Marketed formulations analyzed.

S. No.	CATAGOTY/ Name of Product	Manufacturer	Batch No.	Mfg. Dt.	Exp. Dt.
A.	***ARISHTA***				
1.	Ashokarishta (450 ml)	Dabur India Ltd.	BD1615	02/2014	-
2.	Ashokarishta (450 ml)	Unjha Pharmaceutical Ltd.	A-1401	01/2014	-
3.	Ashokarishta (450 ml)	Divya Pharmacy	ASK034	05/2013	-
4.	Ashwagandharishta (450 ml)	Dabur India Ltd.	BD0278	07/2012	07/2017

5.	Ashwagandharishta (450 ml)	Unjha Pharmaceutical Ltd.	A-1401	01/2014	-
6.	Ashwagandharishta (450 ml)	Divya Pharmacy	ASG084	04/2014	-
B.	***ASAVAS***				
7.	Lohasava (450 ml)	Dabur India Ltd.	SB0139	07/2010	07/2015
8.	Lohasava (450 ml)	Unjha Pharmaceutical Ltd.	J-1101	10/2011	-
9.	Lohasava (450 ml)	Patanjali Ayrveda Ltd.	PL-103	11/2013	-
C.	***VATI***				
10.	Yograj Guggul (60 N)	Dabur India Ltd.	SB0405	02/2014	02/2019
11.	Yograj Guggul (40 Tab)	Unjha Pharmaceutical Ltd.	A-1201	07/2013	-
12.	Yograj Guggul (40 gm)	Divya Pharmacy	YRG005	08/2013	08/2018
13.	Arogyavardhini vati (40N)	Dabur India Ltd.	SB0144	04/2014	04/2017
14.	Arogyavardhini vati (40 Tab)	Unjha Pharmaceutical Ltd.	B-1401	03/2014	-
15.	Arogyavardhini vati (20gm)	Divya Pharmacy	AVV010	08/2013	08/2018
D.	***CHURNA***				
16.	Triphla churna (120 gm)	Dabur India Ltd.	AL1388	05/2014	05/2016
17.	Triphla churna (100 gm)	Unjha Pharmaceutical Ltd	L-1302	12/2013	12/2015
18.	Triphla churna (20 gm)	Divya Pharmacy	TPC116	08/2013	03/2016
19.	Ashwagandha churna (60 gm)	Dabur India Ltd.	AL0155	01/2014	01/2016
20.	Ashwagandha churna (100 gm)	Unjha Pharmaceutical Ltd.	A-1401	01/2014	01/2016
21.	Ashwagandha churna (100 gm)	Divya Pharmacy	AGC001	04/2014	03/2016
E.	***BHASMA***				
22.	Shankh bhasma (5 gm)	Dabur India Ltd.	SB0116	06/2013	06/2018
23.	Shankh bhasma (10 gm)	Unjha Pharmaceutical Ltd.	A-1201	05/2012	05/2015
24.	Shankh bhasma (5 gm)	Divya Pharmacy	SKB036	03/2014	-
25.	Mandoor bhasma (5gm)	Dabur India Ltd.	SB0082	04/2012	04/2017
26.	Mandoor bhasma (10 gm)	Unjha Pharmaceutical Ltd.	A-1301	08/2013	-
27.	Mandoor bhasma (5gm)	Divya Pharmacy	MDB001	07/2012	-
28.	Lauh bhasma (5 gm)	Dabur India Ltd.	SB0053	11/2011	11/2016
29.	Lauh bhasma (5 gm)	Unjha Pharmaceutical Ltd.	2	12/2013	-
30.	Lauh bhasma (5 gm)	Divya Pharmacy	LHB005	07/2012	-

F.	***AVALEHA***				
31.	Chyavanprash (250 gm)	Dabur India Ltd.	PN2447	07/2012	07/2015
32.	Chyavanprash (500 gm)	Unjha Pharmaceutical Ltd.	K-1303	11/2013	11/2016
33.	Chyavanprash (500 gm)	Divya Pharmacy	PSCH064	02/2014	01/2017

Table 2: Ayurvedic formulations with uses

S. No.	Name of formulation	Uses
A.	***Arishta***	
1.	Ashokarishta	All types of menstrual disorders
2.	Ashwagandharishta	Irritation, restlessness, fatigueness, useful in hysteria and general debility
B.	***Asava***	
3.	Lohasav	Iron deficiency, improves blood formation, general weakness
C.	***Vati***	
4.	Yograj Guggul	Osteoarthritis and other joints pain
5.	Arogyavardhini vati	Skin, liver disorder, obesity & chronic fever etc.
D.	***Churna***	
6.	Triphala churna	Constipation, indigestion, eye health
7.	Ashwagandha churna	To improve strength & stamina
E.	***Bhasma***	
8.	Shankh Bhasma	Indigestion, Flatulence, Abdominal pain and hyperacidity
9.	Mandoor Bhasma	Anaemia, jaundice, piles, intestinal worms, liver and spleen enlargement
10.	Lauh Bhasma	Anaemia, liver enlargement and spleen and associated Weakness
F.	***Avaleh***	
11.	Chyavanprash	Cough, bronchial asthma, geriatric disorders, loss of
		appetite, loss of memory, disorders of lungs, ear, nose and throat

2.1 Physical evaluation

All the Ayurvedic formulations were evaluated by determining their physical parameters. These parameters include alcohol content, water and alcohol soluble extractive, pH, total solid content, density, surface tension and viscosity, loss on drying, moisture content, total ash, acid insoluble ash, water soluble ash, loss on ignition etc. [11, 12].

2.1.1 Determination of alcohol content, total solid content, viscosity and specific gravity

Values of Alcohol content, total solid content, viscosity and specific gravity for the liquid preparation were determined as per the method described in Indian Pharmacopoeia.

2.2.2 Determination of pH

The pH value of preparation was determined by using a digital pen type pH meter. It was calibrated by using Buffer tablet pH 4.0 and pH 7.0 and then pH of formulation was determined.

2.2.3 Determination of relative surface tension

Surface tensions of the liquid samples were determined by using Stalagmometer.

2.2.4 Determination of ash values and extractive values

Values of total ash, acid insoluble ash and water soluble ash and alcohol & water soluble extractive values were determined as per Indian Pharmacopoeial methods.

2.2.5 Determination of moisture content, loss on drying and loss on ignition

Determination of moisture content and loss on drying was done by hot air oven method while loss on ignition was done by muffle furnace. Loss on drying determines the percentage of volatile matter driven off from the sample while loss on ignition evaluates the portion of organic matter present in the samples.

2.2 Quantitative estimation of lead

Analysis of heavy metal contamination in most matrices was done by atomic absorption spectroscopy (AAS) and this method was used in the analysis of lead. The samples were prepared from Ayurvedic formulations of different categories.

2.2.1 Preparation of standard solutions from lead atomic absorption 1000 part per million (ppm) standard stock solution

Lead standard solution: Lead standard solutions were prepared from Stock solution (1000 ppm Sisco Research Laboratories Pvt. Ltd.). Standard solutions of concentrations 2, 4, 6, 8, 10 ppm were prepared. The absorption of standard solution measured at 217 nm using Atomic absorption Spectrophotometer. The results are expressed in **table 3** and **fig 1** expresses graph of absorbance of stock solution of lead.

Table 3: Concentration and Absorbance of Lead

Solution No.	Concentration (ppm)	Absorbance
1.	2.00	0.043
2.	4.00	0.127
3.	6.00	0.223
4.	8.00	0.294
5.	10.00	0.361

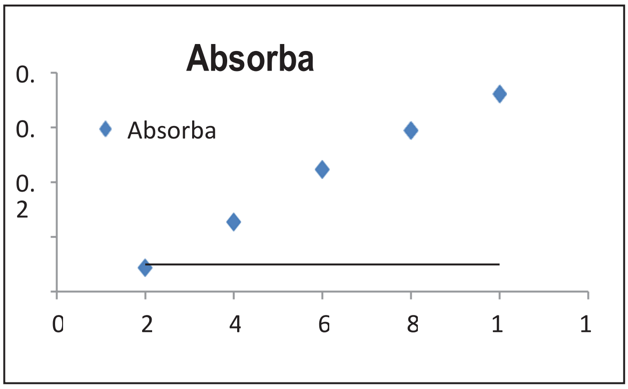

Fig 1: Absorbance of stock solution of lead

2.2.2 Digestion of samples

2.2.2.1 For solid preparations

Samples were digested by the wet digestion method. 10 ml of nitric acid was added to 2 g of accurately weighed dried sample in a 100 ml beaker and was heated on a hot plate at 95°C for 15 min. The digest was cooled and 5 ml of concentrated nitric acid was added and heated for additional 30 min at 95°C. The last step was repeated and the solution was reduced to about 5 ml without boiling. The sample was cooled again and 2 ml of de-ionized water and 3 ml of 30% hydrogen peroxide was added. With the beaker covered, the sample was heated gently to start the peroxide reaction. If effervescence becomes excessively vigorous, sample was removed from the hot plate and 30% hydrogen peroxide was added in 1 ml increments, followed by gentle heating until the effervescence was subsides. 5 ml of concentrated hydrochloric acid and 10 ml of deionized water was added and the sample was heated for additional 15 min without boiling. The sample was cooled and filtered through a

Whatmann No. 42 filter paper and diluted to 50 ml with de-ionized water [13].

2.2.2.2 For Liquid preparations

An accurately weighed 5 ml of Arishta and Asava was taken in round bottom flask. 5 ml of concentrated nitric acid was added and refluxed for half an hour on a hot plate at 60-80°C. It was then cooled; 5 ml of concentrated nitric acid was added and warmed on water bath. 2 ml of 30% hydrogen peroxide solution was added to the above mixture and warmed till clear solution was obtained. It was then cooled and filtered through Whatmann-42 filter paper, diluted with deionized water and made up to 100 ml in volumetric flask [1].

2.3 Sample analysis

The analysis of the digested samples was carried out using a Atomic absorption spectrophotometer (EC Electronics Corporation of India Limited AAS Element AS AAS4141) for lead. The instrumental conditions for lead analysis are as in **table 4:**

Table 4: Instrumental conditions for Lead analysis

Instrumental Parameters		
Wavelength (nm)	:	217
Slit width (nm)	:	1.0
Flame type	:	Air/ C_2H_2
Current	:	10
AAS technique	:	Flame

3. Result and Discussion

In present research work, the parameters of about 33 formulations of different categories were evaluated as per the standards given by Ayurvedic Pharmacopeia, Indian Pharmacopeia, AYUSH and WHO. The estimation of heavy metal, lead was done by atomic absorption

spectrophotometer (AAS) using the instrumental conditions given in table 4. The permissible limit of lead in herbal preparations is 10 ppm according to WHO and AYUSH. Arishta and Asava are fermented liquid preparations while Guggul and vati are solid dosage form (tablet formulation). Churna is fine powder while Bhasma is very fine powder form. Chyavanprash is Avaleha, which is a semi solid preparation. Results of physical parameters are mentioned in **table 5 to 9**.

Table 5: Physical Parameters of Liquid Preparations

S. No.	Tests	Ashokarishta			Ashwagandharishta			Lohasav		
		Dabur	Unjha	Divya	Dabur	Unjha	Divya	Dabur	Unjha	Divya
1.	Description	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
a.	Colour	Light brown	Brown	Dark brown	Brown	Light brown	Dark brown	brown	Light Brown	Dark brown
b.	Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
c.	Taste	Sweet	sour	sour	sour	sour	sweet	sour	sour	sour
2.	pH	4.1	4.4	4.0	3.7	3.7	3.7	3.7	3.7	3.7

3.	Specific gravity (wt/ml)	1.0392	1.0245	1.1223	1.0181	1.0250	1.1276	1.0362	1.0169	1.1269
4.	Total solid content (%w/v)	20.04 %	13.19 %	37.46 %	20.85 %	12.27 %	45.66 %	26.13 %	7.66%	40.83 %
5.	Alcohol content (%v/v)	32 .88%	22.16 %	31.32 %	19.24 %	2.64%	34.44 %	16.36 %	28.20 %	2.64%
6.	Viscosity (cps)	2.6915	2.8993	3.636	2.8710	2.7470	4.4089	2.7977	2.6134	3.5271
7.	Relative Surface tension	0.5402	0.5069	0.5998	0.4821	0.5487	0.6695	0.5479	0.5696	0.6598

Table 6: Physical Parameters of Vati

S. No.	Tests	Yograj Guggul			Arogyavardhini Vati		
		Dabur	**Unjha**	**Divya**	**Dabur**	**Unjha**	**Divya**
1.	Description	Solid	Solid	Solid	Solid	Solid	Solid
a.	Color	Brown	Dark Brown	Dark Brown	Brown	Brown	Dark Brown
2.	pH	6.4	4.9	5.0	4.6	4.7	5.1
3.	Loss on drying (%w/w)	7.68%	4.54%	5.54%	2.18%	4.28%	4.38%
4.	Moisture content (%w/w)	5.1%	5.54%	4.52%	3.66%	4.48%	4.9%
5.	Total ash (%w/w)	0.34%	0.12%	0.04%	18.68 %	16.88 %	17.44%
6.	Acid insoluble ash (%w/w)	55.83 %	53.39%	56.53%	44.67 %	36.98 %	39.40%
7.	Water soluble ash (%w/w)	97.64 %	98.74%	98.82%	1.31%	2.72%	1.17%
8.	Loss on ignition (%w/w)	78.33 %	91.24%	84.96%	1.03%	.01%	3.48%
9.	Alcohol soluble extractives (%w/w)	1.32%	4.44%	5.16%	4.64%	3.32%	5.48%
10.	Water soluble extractives (%w/w)	17.28 %	14.8%	18.2%	17.76 %	17.92 %	21.04%

Table 7: Physical Parameters of Churna

S. No.	Tests	Triphla churna			Ashwagandha churna		
		Dabur	**Unjha**	**Divya**	**Dabur**	**Unjha**	**Divya**
1.	Description	Powder	Powder	Powder	Powder	Powder	Powder
a.	Color	Light Brown	Brown	Brown	Light Brown	Light Brown	Light Brown
2.	pH	3.2	3.5	3.4	5.7	5.5	5.7
3.	Loss on drying (%w/w)	5.2%	5.42%	7.28%	1.76%	1.76%	4.32%
4.	Moisture content (%w/w)	7.42%	8.08%	10.08%	5.02%	5.6%	7.42%
5.	Total ash (%w/w)	3.52%	4.44%	3.36%	6.06%	5.52%	5.1%
6.	Acid insoluble ash (%w/w)	99.92%	99.91%	99.92%	65.57%	93.15%	63.90%
7.	Water soluble ash (%w/w)	8.96%	12.31%	9.85%	65.67%	43.84%	59.60%
8.	Loss on ignition (%w/w)	97.06%	95.89%	97.07%	94.54%	94.79%	95.09%
9.	Alcohol soluble extractives (%w/w)	8.88%	10.44%	9.04%	2.88%	1.80%	2.60%
10.	Water soluble extractives (%w/w)	11.16%	30.16%	32.52%	22.12%	11.28%	15.64%

Table 8: Physical Parameters of Bhasma

S. No.	Tests	Shankh Bhasmna			Mandoor Bhasma			Lauh Bhasma		
		Dabur	**Unjha**	**Divya**	**Dabur**	**Unjha**	**Divya**	**Dabur**	**Unjha**	**Divya**
1.	Description	Fine powder	Fine powder	Fine powder	Fine powder	Fine powder	Fine powder	Fine powder	Fine powder	Fine powder
a.	Colour	White	White	White	Brown	Brick red	brown	brown	Brick red	brown
2.	pH	12.1	10.4	11.9	5.9	7.5	7.4	5.9	6.9	7.6
3.	Loss on drying (%w/w)	0.48%	0.56%	0.20%	0.36%	1.68%	2.36%	1.12%	1.24%	0.44%
4.	Moisture content (%w/w)	0.20%	0.92%	0.44%	2.04%	2.88%	2.2%	0.68%	0.60%	0.80%
5.	Total ash (%w/w)	63.2%	51.0%	57.84%	98.36%	97.28%	98.24%	85.84%	97.4%	97.48%
6.	Acid insoluble ash (%w/w)	0.0%	0.0%	0.0%	84.05%	69.38%	76.50%	68.36%	69.16%	92.24%

7.	Water soluble ash (%w/w)	17.86 %	25.72 %	12.18 %	9.26%	12.77 %	8.03%	0.65%	14.10 %	20.28 %
8.	Loss on ignition (%w/w)	36.62 %	43.24 %	43.01 %	4.06%	3.86%	3.26%	0.08%	0.86%	1.2%
9.	Alcohol soluble extractives (%w/w)	1.73%	0.53%	1.06%	1.33%	1.33%	1.53%	2.2%	0.86%	1.2%
10.	Water soluble extractives (%w/w)	6.46%	2.0%	13.06 %	2.46%	2.66%	3.73%	1.12%	2.4%	2.93%

Table 9: Physical Parameters of Avaleha (Chyavanprash)

S. No.	Tests	Chyavanprash		
		Dabur	**Unjha**	**Divya**
1.	Description	Semi solid	Semi solid	Semi solid
a.	Colour	Dark brown	Dark brown	Dark brown
b.	Odour	Pleasant	Pleasant	Pleasant
c.	Taste	Sweet	Sweet	Sweet
2	pH	3.7	3.8	3.7
3.	Loss on drying (%w/w)	21.86%	17.95%	15.12%
4.	Total solid content (%w/w)	22.38%	18.24%	17.42%
5.	Total ash (%w/w)	0.59%	0.13%	0.38%
6.	Acid insoluble ash (%w/w)	0%	0%	0%
7.	Alcohol soluble extractives (%w/w)	18.66%	24.16%	2.93%
8.	Water soluble extractives (%w/w)	57.64%	61.86%	51.87%

The all values of lead concentration are listed in **table-10**. Graphical representations of lead concentration, in ppm of different formulations by comparison in three different brands, are expressed in **Fig 2.** Maximum tolerable limit is 10 ppm. Heavy metal lead was found within the permissible limit.

Table 10: Trace Element (Lead) Concentration in Herbal Ayurvedic Products (ppm)

S. No.	Code	Formulations	Brands		
			Dabur	Unjha	Divya
1	A	Ashokarishta	2.142	2.229	2.026
2	B	Ashwagandharishta	1.810	0.318	1.785
3	C	Lohasav	1.385	0.145	2.423
4	D	Yograj guggul	1.762	2.923	2.981
5	E	Arogyavardhini Vati	1.505	2.923	2.506
6	F	Triphla Churna	0.145	0.145	0.753
7	G	Ashwagandha Churna	0.145	0.145	0.260
8	H	Shankh Bhasma	0.402	1.852	2.013
9	I	Mandoor Bhasma	2.851	4.370	2.779
10	J	Loah Bhasma	2.373	2.538	3.184
11	K	Chyavanprash	3.242	3.242	3.618

Graphical representations of lead concentration, in ppm of different formulations by comparison in three different brands, are expressed in **Fig 2.** Heavy metal lead was found within the permissible limit.

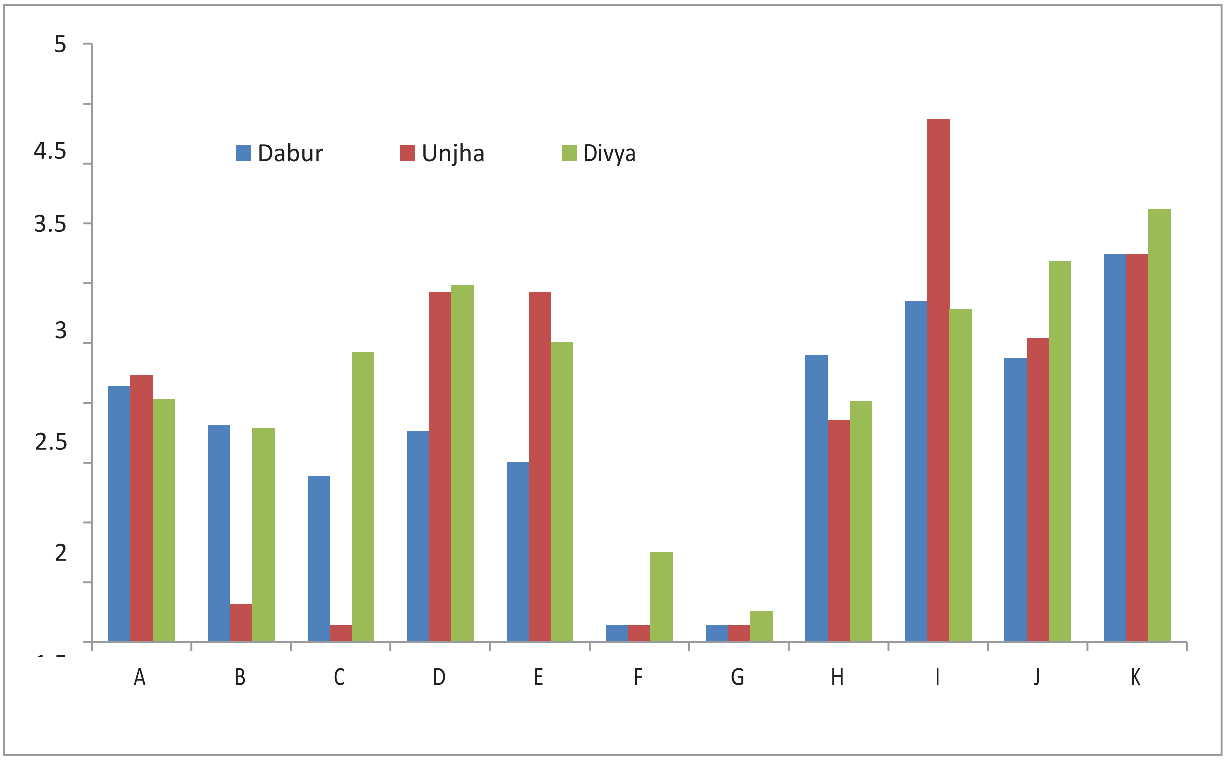

Fig 2: Graphical representation of lead concentration, in ppm of different formulations by comparison in three different brands. Maximum tolerable limit is 10 ppm.

[A: Ashokarishta; B: Ashwagandharishta; C: Lohasav; D: Yograj guggul; E: Arogyavardhini Vati; F: Triphla Churna; G: Ashwagandha Churna; H: Shankh Bhasma; I: Mandoor Bhasma; J: Loah Bhasma; K: Chyavanprash]

4. Conclusion

It was concluded that almost all the categories of formulations complied with the standard parameters given by the above mentioned reference books. The major herbal manufacturers are aware of the standardization of their preparations. All the Ayurvedic preparations of different categories are of helpful to impart beneficial therapeutic effects. Although these all have some of trace of heavy metal content but lead found appreciably below the permissible limit. All Ayurvedic formulations fulfill the quality control aspects of limit of Lead as heavy metal. One cannot blame the entire Herbal system of medicines by the case studies proving that all the herbal medicines are responsible for the heavy metal toxicity. Still there is a need to strengthen the regulatory and quality control aspects so as all the herbal drug strictly complies with the specifications given in the Reference books and international Drug regulatory agencies.

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