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Detecting the Heavy Metals Content to Ensure Safety in Oriens® Nephrofit – A Nutraceutical Combination

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Abstract: ***Heavy metals are natural constituents of the Earth's crust.In heavy-metal-polluted soils; plant growth can be inhibited by metal absorption which represents a potential risk for animals and humans. Natural extracts, besides it's sought after pharmacological effect and uses in medical treatment, could be dangerous because of heavy metals and pesticides. The aim of this study is to investigate and detect the heavy metal content in our Oriens® Nephrofit product to ensure safety. In this study, the content of heavy elementswas determined using atomic absorption spectrometermethod.The results were compared with the FSSAI safety limits and were found to be within the permissible limits. This study highlight that the content of heavy metals of manufacturing capsule does not exceed the safety limits and its concentration is far below the permissible limits, thus ensuring safety.***

Keywords: Heavy metals, Nutraceuticals, Oriens® Nephrofit, Permissible limit

1. Introduction

Nutraceuticals are particularly of interest to the present generation because they have the potential to substantially reduce the expensive, high tech, disease treatment approaches presently being employed in western healthcare. Primarily used in functional foods and dietary supplements, nutraceutical ingredients are natural bioactive, chemical compounds that have health promoting disease preventing or medicinal properties.

In ancient times nature has been an important source of medicinal agents and a large number of natural products have been identified and developed from natural sources based on their use in traditional medicine. Numerous medicinal plants are of global interest today because of their therapeutic and economic significance. According to the World Health Organization, approximately 80% of the world's population currently uses herbal medicines directly as teas, decocts or extracts with easily accessible liquids such as water, milk, or alcohol.

Global and national markets for nutraceutical products have been growing rapidly. As a consequence, the safety and quality of the nutraceutical products have become increasingly important concerns for health authorities and the public alike. Heavy metal contamination of food items is one of the most important considerations in food quality assurance (Marshall, 2004). These metals may reach and contaminate plants, vegetables, fruits and canned foods through air, water and soil during cultivation (Husain *et al* 1995) and also during industrial processing and packaging.

Contamination of food products by heavy metals is becoming an unavoidable problem these days (Zukowska and Biziuk, 2008). Contamination by heavy metals could be due to contaminated soil, pesticide applications, fertilizers, or industrial activities. Heavy metal contamination is a global challenge because herbal product contaminations with heavy metals have been reported in many countries (Obi *et al* 2006, Kalny *et al* 2007,Tumir, 2008, Acre *et al* 2005).

Heavy or toxic metals are stable elements and bio-accumulative. These include: mercury, nickel, lead, arsenic, cadmium, aluminium, platinum, and copper. Heavy metal pollutants can contaminate the products during processing by inhalation of air and penetration through the skin's surface (Raikwar *et al* 2008).Hence, during the manufacturing process of dietary supplements, the manufacturing companies should take most or all the quality assurance measures to avoid contamination due to heavy metals (Liva, 2007).

Applying food safety standards on a product is very important because it relates closely to human's health. Good food products have a high nutritional quality, as well as being free from physical, chemical and biological contaminations. The food industry development encourages food manufacturer's to produce more practical and durable products, but still must have high nutrition (Hamasalim. H. J; Mohammed. H. N., 2013).

Thus, the aim of this study is to investigatethe heavy metal content in our formulated nutraceutical product Oriens® Nephrofit to ensure safety and to highlight any consequent health concern.

2. Materials and Methods

2.1 Methodology

Heavy metal analysis using atomic absorption spectrophotometer

A Heavy metal is a member of a loosely-defined subset of elements that exhibit metallic properties. It mainly includes

the transition metals, some metalloids, lathanides and actinides.

The Heavy metals in Oriens® Nephrofit were analyzed. The heavy metals such as iron (Fe), zinc (Zn), copper (Cu), manganese (Mn), nickel (Ni), lead (Pb) and cadmium (Cd) were detected (API, 2008).

Organic matter in sample was digested by wet digestion or dry digestion or high pressure microwavedigestion and determine the amount of heavy metals, i.e. arsenic (As), cadmium (Cd), lead (Pb) and mercury (Hg) by using graphite furnace atomic absorption spectrophotometer (GF-AAS) and flowinjection analysis system -atomic absorption spectrophotometer (FIAS-AAS).

2.2 Sample Preparation

Prepare the Reagent Blank as in sample preparation but without adding the sample. Dilute 5 ml of distilled water and 5 ml of concentrated sulphuric acid, place it for 24 hours without disturbing.

Microwave digestion (for As, Cd, pb, Hg)
About 0.15 – 0.20 gm of sample was accurately weighed into a high pressure resistance 50 ml quartz or TFM vessel. 3 ml of conc. nitric acid and 1 ml of 30 % hydrogen peroxide 1 ml were added by using graduated pipette. If sample contain talcum or pigment 1 ml of conc. hydrochloric acid was added. The vessel lid was closed. To ensure complete reaction left it for about 15 minutes. At the specified program digested in microwave digestion system. After cooling to room temperature, 20 ml of deionised water was added to the digested solution, rinse the inner wall and lid thoroughly. Filtered through Whitman paper no.1 into 50 ml volumetric flask and dilute to volume with deionised water.

Dry ashing (for As, Cd, pb)
2.5 g sample was accurately weighed into a silica dish and 3 ml of 50% w/v magnesium nitrate was added . Dried on the water bath and ash the residue first in the heating mantle until no more fume and then in the muffle furnace at 500° C for 3 hours. Allowed it to cool and then 25 ml 6M hydrochloric acid was added, filtered into a 50 ml volumetric flask and diluted to volume with water.

Wet digestion (for Hg)
0.5 g sample was weighed into a digestion tube with screw cap and 7ml of conc. nitric acid was added. Maximum for at least 3 hours heated the sample solution in a block heater at 60°C, allowed it to cool and diluted to volume (50 ml) with water. Kept it stand for 24 hours in the refrigerator. Filtered the solution through the Whatman paper No. 40. The digested solutions were used for analyses by FIAS-AAS (cold vapour mercury technique).

Pre-treatment for As
10 ml each of deionised water (as standard blank), the reagent blank, the standard solutions and the sample solution was pipette out into separate 100 ml volumetric flasks. 10 ml of concentrated hydrochloric acid and 10 ml of reagent was added for pre-treatment of As to each of the solutions and allowed them to stand for 45 minutes at ambient temperature. It was diluted to volume with water. The final concentrations of the standard solutions were 2.0, 4.0, 6.0 and 8.0 µg/l respectively. These solutions were used for analyses by FIAS-AAS (Hydride Generation Technique).

Calibration curve
Standard calibration solutions was injected into the GF-AAS or FIAS-AAS (Cold vapour Technique) or FIAS-AAS (Hydride Generation System) at the specified condition. The response (absorbance or peak height or area) versus concentration of each standard solution was plotted. Injected the sample solutions into GF-AAS or FIAS-AAS (Cold vapour Technique) or FIAS-AAS (Hydride Generation System). Recorded the response and concentration (µg/L) of As, Cd, pb, and Hg in sample solution, then calculated µg/g of As, Cd, pb, Hg in sample.

2.3 Calculation

$$\text{As cd pb Hg} = \frac{\text{Conc .of As,cd,pb,Hg in sample solution} \times \text{ml of sample}}{\text{Sample weight} \times 1000} \ \mu g/g$$

3. Results and Discussion

Oriens® Nephrofit is a combination of Crataeva nurvala extract and piperine. *Crataeva nurvala*is commonly known as Varuna. Varuna is one of the best litholytic herbs and has been used throughout the ages for the treatment of urolithiasis and crystalluria. Piperine is extracted from peppers; Piperine may help to increase the availability of key nutrients. It may also be useful for additional purposes such as support for weight and stress management.

Heavy metals have been widely acknowledged to adversely affect the nutritive values of agricultural produce on account of their deleterious effect on human beings. As such, an increasingly important aspect of food quality assurance has been to control theconcentrations of heavy metals in food (Sobukola *et al* 2010). We aimed to study the heavy metal content in *Nephrofit* capsules from Oriens Global Marketing (P) Ltd using the Atomic absorption method. The results obtained are tabulated in Table 1 below.

Table 1: Heavy metal analysis in Oriens® Nephrofit

Test Parameters	Sample - Oriens® Nephrofit (VNL18-017)	FSSAI Limit
Heavy Metals (mg/kg) - Results		
Hg(mg/kg)	0.0132	0.5
As(mg/kg)	0.0133	1.1
Cd(mg/kg)	BDL	1.5
pb(mg/kg)	BDL	2.5

The heavy metals such as lead, arsenic, cadmium, and mercury were analyzed by atomic absorption spectrophotometry. In the formulated nutraceutical product - heavy metals like cadmium, arsenic, mercury, and lead were found to be within the prescribed limits. The heavy metals were compared with FSSAI limit and were found to be below the prescribed limits. Thus the products were free from Heavy metals and were safe to use.

4. Conclusion

We found that this study shows there is no presence of toxic heavy metals like arsenic, cadmium, lead and mercury in the *Oriens® Nephrofit*. It represents that *Oriens® Nephrofit* are found to be free from heavy metal contaminations. Therefore this study concludes that there is no possible health risk to humans due to heavy metals to consume this product *Oriens® Nephrofit* and it is said to be tested for safe consumption.

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