

Comparative elemental analysis of Kushtae Sadaf, a *Unani* formulation

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Abstract

Background: Kushta is one of the most important dosage forms in the *Unani* system of medicine. Kushtae Sadaf is rich in calcium, iron, and copper, and it is used in the treatment of so many systemic disorders such as cardiac problem, sexual disability, and renal disorder. Number of *Unani* pharmaceutical companies manufactures Kushtae Sadaf. Preparation of Kushta is a little bit difficult and if it is not prepared under keen observation, it may be harmful to the patients instead of providing relief. **Materials and Methods:** In the present study, a pharmacopeial *Unani* formulation namely Kushtae Sadaf was under taken evaluated to identify the elements present in Kushtae Sadaf prepared by two different methods. One market sample was also evaluated for same elements along with two in-house prepared samples. **Results:** All the three samples were subjected to elemental analysis, and the results were found to be as follow. Calcium was found to be more in Kushtae Sadaf Furnace Method (KSFM) which was 47.79%, whereas it was 44.52% and 42.19% in Kushtae Sadaf Classical Method (KSCM) and Kushtae Sadaf Market Sample (KSMS), respectively. Iron was found to be 235.8 ppm, 294 ppm, and 998.1 ppm in KSCM, KSFM, and KSMS, respectively. Copper was found to be <0.1 ppm, 2.98 ppm, and 1 ppm in KSCM, KSFM, and KSMS, respectively. Bromide was found to be 10 ppm and 5.3 ppm in KSCM and KSFM, respectively, and it was not detected in KSMS. Heavy metals (lead, cadmium, mercury, and arsenic) were found to be below the permissible limits given by the WHO in KSCM, whereas in KSFM, lead was found to be 28.7 ppm which is above permissible limit. In KSMS, two heavy metals namely mercury and arsenic were found to be 112 ppm and 12.3 ppm, respectively, which is above permissible limits and other two heavy metals were found to be below the permissible limit namely cadmium and lead.

Key words: *Calotropis gigantea*, heavy metals, Kushta, *Pinctada margaritifera*, Sadaf

INTRODUCTION

In *Unani* medicine, Kushta is an important class among the compound formulation, which is prepared by incinerating prescribed metals, minerals, and animal parts pounded and triturated with recommended amount of plant extract, further subjecting it to the classical incineration method using cow dung cakes. Sadaf (*Pinctada margaritifera*), a marine origin natural shell in its Kushta form, is a remedy for numerous disorders, indicated in cardiac weakness (zouf-e-qalb), leukorrhea (sailan-urrahem), hemorrhage (nazuf-ud-dam), calcium deficiency (qilat-e-kils),^[1] menorrhagia (kasrat-e-tams), fever in tuberculosis (huma-e-sil-odiq), asthma (zeeq-un-nafs), chronic cough (surfa-e-muzmin), sexual debility (zouf-e-bah), hemorrhoids (bawasir), and indigestion (zouf-e-hazam).^[2] It contains various minerals such as calcium, iron, copper, and bromide

necessary for the human body.^[3] With the advancements and progressions in every specialty of the science, the process of Kushta preparation has also changed and adapted the modern techniques. Adaptation of wrong manufacturing methods of dosage forms, especially Kushta may lead to the toxicity. Thus, in view of the clinical significance of Kushtae Sadaf, study was carried out to estimate its *in vitro* safety in terms of comparative elemental analysis by in-house preparation with both classical and furnace methods and market sample.

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MATERIALS AND METHODS

Raw Material

The Classical Method of Kushta Sadaf preparation was followed with accordance to the National Formulary of *Unani* Medicine (NFUM).^[1] Sadaf (*P. margaritifera*) was procured from market, and its authenticity was confirmed by experts of the Department of Mollusca, Central Marine Fisheries Research Institute, Kochi. The plant Madar (*Calotropis gigantea*) after the authentication at Foundation for Revitalization of Local Health Traditions, its latex (Sheer-e-Madar) was collected in the early morning by cutting its apex parts. Sirka (synthetic vinegar) for purification purpose was obtained from local market. Voucher specimens of Sadaf and *Calotropis* were deposited in drug museum of National Institute of *Unani* Medicine for future reference. No 17/IS/Res/2014.

Purification and Preparation Process

A complete shell of raw Sadaf was chipped into small pieces of size not exceeding 5 cm × 5 cm in length and breadth [Figure 1], soaked in 1 L of Sirka containing 4% acetic acid for 24 h. After 24 h, the same was heated for 3 h.^[4] Thereafter, Sadaf was removed and washed with hot water and purified Sadaf was isolated. Then, purified Sadaf was powdered using mortar and pestle. Further, Sheer-e-Madar was added to it, just above the powder level and left until dry. The pellets were made by adding small amount of distilled water to the dried matter obtained after trituration and powdering of Sadaf with Sheer-e-Madar. These pellets were kept for drying at room temperature for 2 days. One group of pellets were subjected to the classical method of 20 kg cow dung cakes as mentioned in NFUM^[1] with slight modification [Figure 2] and another group were subjected to modern furnace method [Figure 3]. The temperature and the duration which was recorded in the classical method were tried to maintain with the furnace method [Figures 4 and 5].

Quantitative Estimation of Elements

Quantitative estimation of the selective elements, i.e., calcium, iron, copper, lead, mercury, arsenic, cadmium, and bromide in all the three samples, Kushta Sadaf prepared by Classical Method (KSCM), Kushta Sadaf prepared by Furnace Method (K.S.F.M), and Kushta Sadaf of Market Sample (K.S.M.S) were carried out in Bangalore Test House under the guidance of experts. Calcium was estimated by titration method. Iron, copper, lead, mercury, arsenic, and cadmium were analyzed with the help of inductively coupled plasma optical emission spectrometry, Agilent 700 series. Bromide was estimated by ion-chromatography (IC) technique using metrohm apparatus was used for IC.



Figure 1: (a) Raw Sadaf before purification. (b) Sadaf after boiling in Sirka. (c) Sadaf after washing in hot water



Figure 2: Pellets before and after ignition in classical method



Figure 3: Pellets before and after ignition in furnace method



Figure 4: Estimation of calcium by titration

OBSERVATION AND RESULTS

Calcium was found to be high in the K.S.F.M (47.79%) while compared to the K.S.C.M and the K.S.M.S [Figure 4], iron was

found to be high in the KSMS (998.1 ppm) and the copper was little bit high in the KSFM (2.98 ppm) while compared with the remaining sample, respectively. Bromide was found to be below the permissible limit in K.S.C.M and KSFM samples and not detected in KSMS. [Figure 5].

Heavy metals, i.e., lead, mercury, arsenic, and cadmium in all the three samples were found to be as following. Lead was found to high in KSFM (28.7 ppm) while compared to the remaining samples. Mercury was found to be above the permissible limit in the KSMS (112 ppm) but remain below the permissible limit in two in-house preparations. Arsenic was also found to be above the permissible limit in the KSMS (12.3 ppm) and in two in-house preparations, it was detected below the permissible limit. Cadmium was found to be <0.1 ppm in all the three samples, respectively [Figure 6].

DISCUSSION

Calcium percentage by titrimetric analysis done in KSCM, KSFM, and KSMS were in accordance with the previous observations. A study done by Dubey *et al.* confirmed the presence of calcium as the major element in Kushta of same species which was about 40.22 weight%.^[5] In another study carried by Central Council for Research in *Unani* Medicine also suggested the presence of calcium in Kushtae Sadaf in between 39.600% and 40.543%.^[2]

Since, the iron and copper levels present in KSCM and KSFM were below the permissible limits with respect to Food and Agriculture Organization (FAO)/WHO recommendations; their therapeutic consumption can cause no harm. As a guideline, FAO/WHO has defined the permissible limits of the various elements in the consumed medicinal herbs for different countries as iron (261-1239 ppm) and copper (20-150 ppm).^[6] Iron level found in KSMS (998.1 ppm) was quite raised in comparison to the two in-house preparations. Although the value of iron of KSMS was found to be more as compared to two in-house samples, it falls within the permissible limits and hence safe for the therapeutic consumption.

The values of bromide found in KSCM and KSFM were below the permissible limits and in KSMS was below detectable level. Bromide ion possesses low degree of toxicity thus not of toxicological concern in nutrition. FAO/WHO has recommended an acceptable daily intake for humans of 0-1 mg/kg body weight, based on a minimum pharmacologically effective dosage in humans of about 900 mg of potassium bromide, equivalent to 600 mg of bromide ion.^[7]

Heavy metals value of lead, mercury, arsenic, and cadmium in KSCM were also found to be below the permissible limits with respect to the WHO/FAO guidelines.^[8,9] In KSFM, lead value was found to be more than the permissible limit with respect to WHO/FAO guidelines. Although all the steps adopted such as soaking, boiling, cleaning with hot water,

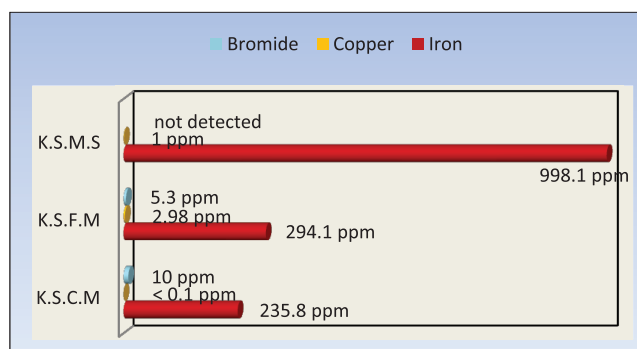


Figure 5: Estimation of iron, copper by inductively coupled plasma optical emission spectrometry and bromide by ion-chromatography

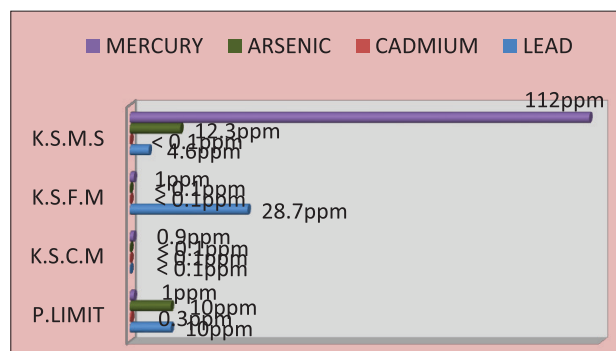


Figure 6: Estimation of heavy metals by inductively coupled plasma optical emission spectrometry

again soaking in plant extract, making of pellets, using of clay crucibles were same in both KSCM and KSFM, the probable reason in the difference of lead values may be due to different incineration methods adopted. The regulation of temperature in furnace method and classical method were differing. Rising of temperature in both the methods were quite similar, but the declining of temperature was not the same. This improper temperature regulation in furnace method could have made the difference in terms of higher lead levels. In KSMS, the presence of mercury and arsenic were above the permissible limits with regard to the WHO/FAO levels, and the values of lead and cadmium were below the permissible limits.

The results obtained in two in-house preparations were mostly below the permissible limits except the level of lead and the possible reasons were discussed. In case of market sample, the results obtained were irregular and inconclusive. The levels of mercury and arsenic were found to be above the permissible limits, and in contrast, the lead level was below the permissible limit. The possible reason behind this irrelevant result may be due to the raw sample used in the procured market sample. The raw sample used may be processed pieces of different species and of adulterant quality. While the Sadaf selected for this study was of single species with reference to the NFUM. The inconclusive results in the market sample also suggest that the procedure adopted by them, i.e., trituration, purification, and proper incineration may not be in exact accordance to the classical text. Since

all the data supported the classical method as every metal found in the permissible limits. So, it has been proved that classical method is the better procedure in case of Kushtae Sadaf and presence of heavy metals below the permissible limits of KSCM suggests it to be more beneficial in any era.

In the present study, all the heavy metals value in Kushtae Sadaf prepared by classical method was found to be below the permissible limits. This result validates the classical procedure of Kushta Sazi being the better procedure than the furnace method. The absence of heavy metal toxicity and the presence of good amount of calcium and iron in Kushtae Sadaf indicate its therapeutic importance. Hence, it is recommended to carry its safety evaluation studies in animal and clinical trials. It is also must for the pharmacies to ensure the safety assurance of heavy metals in their every herbomineral formulations.

CONCLUSION

As all the heavy metals were found to be below the permissible limit in Kushtae Sadaf prepared by classical method. Hence, Classical Kushta Sazi is the better procedure than the modern furnace method in case of Kushtae Sadaf. It may be mandatory for the manufacturers of Kushta to produce the heavy metal limits in their each batch of Kushta.

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