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## Discussion Kernel

Need for comprehensive standardization strategies for marketed *Ayurveda* formulationsVishvanath Narhari Vaidya <sup>a</sup>, A.U. Tatiya <sup>a</sup>, Ashwini Elango <sup>b</sup>,  
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## ABSTRACT

*Ayurveda* is known for the use of poly-herbal formulations and multi-component therapeutics for the management of health and diseases. Several pharmaceutical companies are manufacturing and marketing different Ayurvedic formulations, prepared as per the classical texts and the regulatory standards. However, on a cursory glance, marked variations are observed amongst the same formulations manufactured by different companies. This raises questions on the quality standards. Drugs or formulations are expected to exert a desired biological activity at particular concentrations of their chemical constituents. The overall aim of drug standardization is to ensure the quality, efficacy and uniformity of the products, in terms of their chemical and biological properties, across the manufactures. In this article, the authors intend to open up a discussion on the need for comprehensive standardization strategies for marketed *Ayurveda* formulations taking *Lodhrasavam* (a classical *Ayurveda* preparation) as an example. *Lodhrasavam* procured from six reputed *Ayurveda* drug manufacturers showed significant variations in their sensorial, physico-chemical, chromatographic as well as biological properties. This is a matter of serious concern and need to be addressed effectively to derive better standardization strategies for Ayurvedic formulations.

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## 1. Introduction

*Ayurveda* is one of the Indian Systems of Medicine (ISM), wherein the concepts of 'holism' are logically and intelligently used to understand the wellness (*Svasthya*) and illness (*Asvasthya*) of living organisms. *Ayurveda* predominantly uses herbal products/formulations for the maintenance of health and management of diseases. These formulations are designed and manufactured based on unique principles of *Ayurveda* pharmacology (*Dravyagunashashtra*), which are epistemologically different from the modern pharmacology concepts of molecular medicines. They are expected to exert a 'network pharmacology' (multi-drug-multi-target mode of action) effect [1,2], due to the presence of several bioactive molecules, that is different from the well known and widely studied

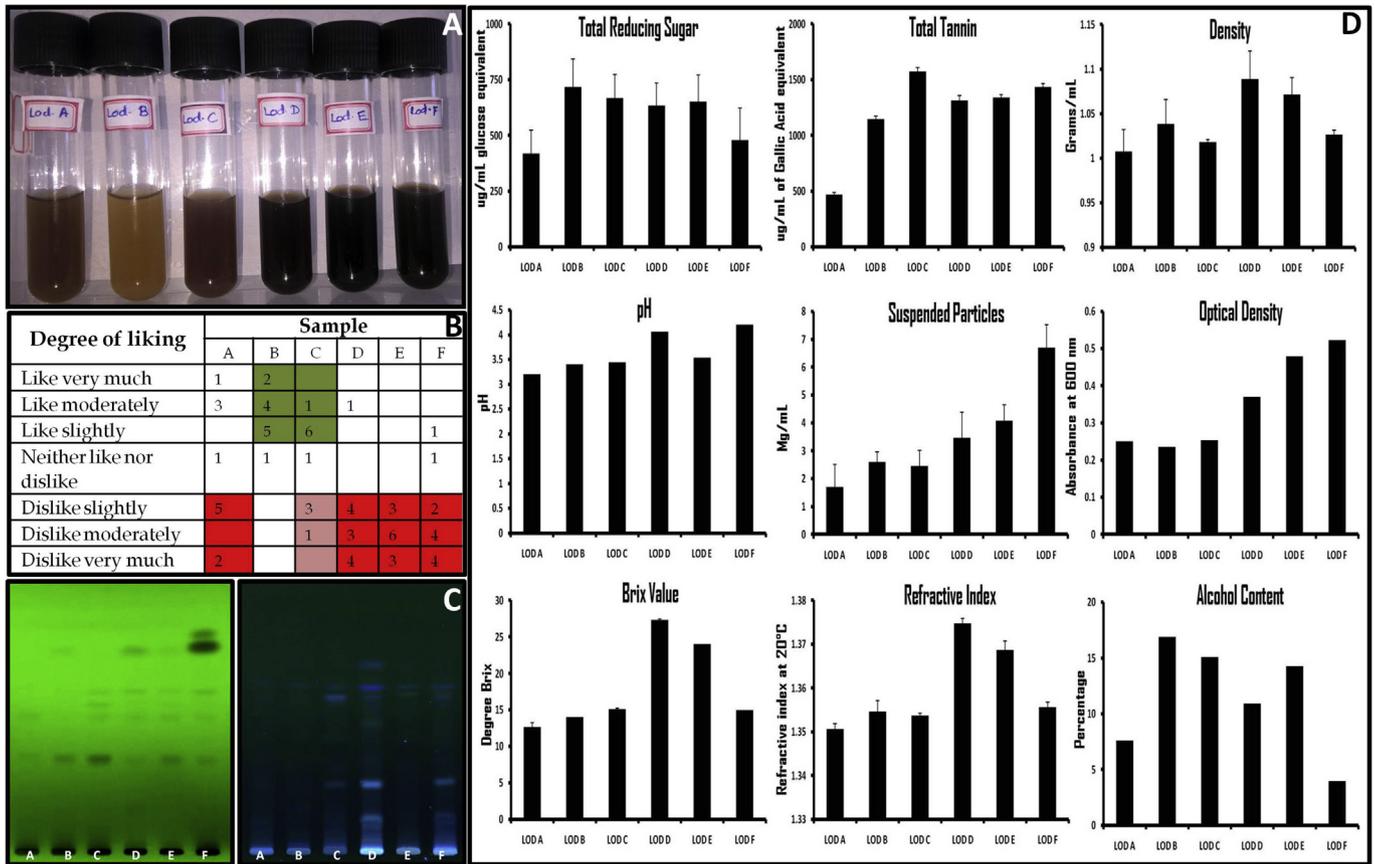
single-drug-single-target action of molecular drugs (lock and key hypothesis) [3,4]. This is considered as one of the strengths of *Ayurveda*, and perhaps for all other complementary and alternative medicines (CAMs) across the globe. However, complexity of the herbal formulations is a major challenge in *Ayurveda* drug industry, making standardization of *Ayurveda* formulation a difficult task. Even a cursory glance of several generic *Ayurveda* formulations produced and marketed by different companies show enormous variations amongst the same product. This raises questions on their quality standards. *Ayurveda* as a science and drug industry, it is very important to follow stringent and non-compromising quality control parameters to ensure uniformity and standards of the formulations/products across the industry. In this context, this article intends to bring out a discussion on the need for better and comprehensive standardization strategies for *Ayurveda* formulations taking the example of the variations observed in marketed samples of *Lodhrasavam*.

The authors are working on the formulation *Lodhrasavam*, focusing on its anti-diabetic and anti-obesity potentials [5].

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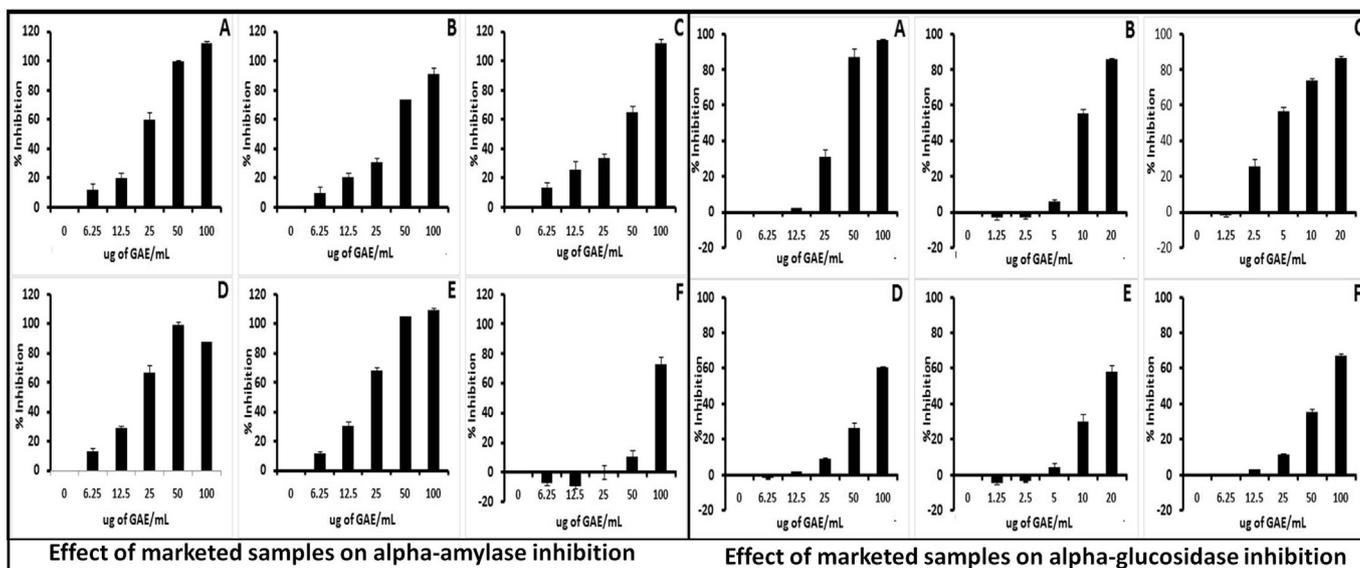
**Fig. 1. Physicochemical and hedonistic comparison of Lodhrasavam samples:** Marketed samples of *Lodhrasavam* (Lod A–F) are compared for (A) – visual appearance; (B) – hedonicity properties; (C) – Thin Layer Chromatography pattern and (D) – physicochemical properties.

*Lodhrasavam* is a complex, poly-herbal formulation prepared from 29 plant drugs, with self generated alcohol in it. *Ayurveda* mentions *Lodhra* (*Symplocos racemosa* Roxb.) as the major ingredient in the formulation, which is referred as a *medo-hara* (anti-obesity) plant and is the prime member of *Lodhradi-gana* plants (a group of plants having *medo-hara* and *kapha-hara* properties) described in *Ayurveda* [6]. Besides the anti-diabetic and anti-obesity applications, *Lodhrasavam* is also indicated for various other diseases such as anaemia,

skin diseases, anorexia, hemorrhoids etc. [7] As part of the sample collection the team collected six marketed samples of *Lodhrasavam*, manufactured by well-known *Ayurveda* drug manufacturers in India. The samples are labeled as LOD A – F. Though our focus was on anti-diabetic and anti-obesity effects of *Lodhrasavam*, the drastic variations in the visual appearance of these marketed samples (Fig. 1A) urged us to do a comparative analysis for their physico-chemical properties as well as biological activities. *Lodhrasavam* is a classical

**Table 1**  
**Predominant sensorial characters of six marketed samples of Lodhrasavam:** Sensorial properties of the marketed samples of *Lodhrasavam* are analyzed based on the organoleptic properties and compared between the samples.

Attributes	Sub-attribute	Lod A	Lod B	Lod C	Lod D	Lod E	Lod F
<b>Attributes for Visual Inspection</b>							
Form	Liquid	Free flowing	Transparent, free flowing	Free flowing like water	Free flowing, little thick	Free flowing, thick	Free flowing, thick, opaque
Color		Greenish brown	Light brown	Dark brown	Dark brown	Dark brown	Dark brown
Uniformity	Presence of Suspended particles	No suspended particles	Settling particles when undisturbed	No suspended particles	No suspended particles; slightly turbid	No suspended particles but froth is seen	Floating particles, turbid
<b>Attributes for Odour Inspection</b>							
Type	Pleasantness and gross nature	Pleasant, sweet & sour odour.	Not pleasant, sweet odour	Sweet odour	Appealing & sweet odour	Sweet odour	Unpleasant odour
Nature/smell	Alcoholic	Alcoholic	Alcoholic	Non alcoholic	Slightly alcoholic	Moderately alcoholic	Slightly alcoholic
	Herbaceous	Herbaceous odour	Not herbaceous	Herbaceous	Slightly Herbaceous	Herbaceous	Slightly Herbaceous
<b>Attributes for Tactile inspection</b>							
Form	Liquid	All samples are free flowing, non sticky and non-viscous liquids					
<b>Attributes for Taste</b>							
Feel	Sharpness	Sharp	Moderate	Sharp	Sharp	Very Sharp	Very Sharp
Taste	Name of predominant taste	Bitter and slightly sweet	Predominantly sweet and slightly sour	Predominantly bitter	Predominantly bitter and slightly sour	Predominantly bitter	Predominantly bitter



**Fig. 2. Comparison of marketed samples of *Lodhrasavam* for its biological activities:** Label A–F indicates the six different marketed samples of *Lodhrasavam*. Data are mean  $\pm$  SEM of three independent experiments done in duplicates and the statistical significance was calculated with controls ( $p$  Value  $\leq$  0.05).

Ayurveda product that is expected to follow a definite method of preparation as indicated by the formulary. According to the product descriptions, all samples are marketed with the product name *Lodhrasavam* and claimed to be prepared in a similar manner as per the classical texts of *Ayurveda*. However, variations are seen in the final products right from simple sensorial parameters. This is large enough to cast doubt on the quality, genuineness and authenticity of the product by the consumers and physicians.

## 2. Comparative analysis of *Lodhrasavam* samples

### 2.1. Hedonicity and physicochemical properties

In view of the visual differences observed, the marketed samples were compared for the degree of likeness (hedonicity), from a consumer perspective, based on taste, odour and palatability. A small amount of the sample was given to 20 healthy volunteers and instructed to report their degree of likeness under any one of the seven classifications given (Fig. 1B). Out of the six samples tested, only sample B and C were found to be appealing by participants wherein 11 people liked sample B and 7 people liked sample C. All other samples were found to be not appealing (Fig. 1B). The samples were also analyzed and compared for their physicochemical properties viz. alcohol content, total reducing sugars and tannins, density, suspended particles, optical density, brix value, refractive index and pH value. The results showed drastic variations in the physicochemical parameters studied and the variations are found to be random and not following any sample-specific pattern (Fig. 1D). Some of the samples are not complying with the prescribed pharmacopoeial limits like alcohol content [8]. Similarly a simple thin layer chromatography (TLC) comparison of the six samples also showed considerable differences in the banding pattern (Fig. 1C), that further substantiates the visual, hedonicity and physicochemical differences observed with the samples. Although it is too early to draw a direct correlation between the hedonicity and physicochemical parameters, it is important to note that the variations are reflected both at the consumer preference level as well as at the physicochemical content level.

### 2.2. Profiling and comparison based on sensory properties

Sensorial profiling is an important aspect for a product as it evaluates the consumer's level of acceptability of the product based on the organoleptic properties. It is more relevant from the consumer perspective as the differences in physicochemical and biological properties are too technical for the consumers to understand. *Lodhrasavam* is an oral medicine and the marketed samples were analyzed and compared for their sensorial properties viz. visual, olfactory, tactile and taste attributes. Substantiating the hedonicity and physico-chemical variations, all attributes/sub-attributes studied, except tactile attributes, were found to be varying between the samples (Table 1).

### 2.3. Comparison of biological activity

*Lodhrasavam* being an anti-diabetic and anti-obesity formulation prescribed in *Ayurveda*, comparison of biological activity of marketed samples was focused on their alpha-amylase and alpha-glucosidase inhibition effects [4]. The variations observed with sensorial, organoleptic and chemical properties are naturally expected to reflect in the biological activity of the formulation as well. Although all the samples showed inhibition of digestive enzymes (alpha-amylase and alpha-glucosidase), there are considerable differences in the percentage of inhibition at specific concentrations of the samples tested (Fig. 2). The variations observed with biological activity is more concerning as it raises questions on the credibility and authenticity of the formulation.

## 3. Conclusion

Drugs and formulations are expected to exert desired biological activities at desired concentrations of its chemical constituents. The overall aim of drug standardization is to have uniformity, across the manufactures, with respect to its chemical and biological properties. Our study basically intend to highlight the variations observed in marketed samples of *Ayurveda* formulations, using *Lodhrasavam* as an example. It is an unbiased study and have no intentions to claim any one of the samples (Lod A–F) is superior to the other. *Lodhrasavam* is just an example, and

similar issues are there with other formulations as well. Though there are several factors that make the standardization of *Ayurveda* formulation a great challenge, drastic variations within the same product will raise questions on the authenticity and credibility of the product. The need of the hour is better standardization protocols and quality measures for uniformity of formulations across the *Ayurveda* drug industry. In the era of globalization of *Ayurveda*, it is necessary to have utmost attention on the quality control parameters for the therapeutic formulations. Our observations are expected to open up discussions on the need of consistency and uniformity of formulations across the *Ayurvedic drug manufacturing industry*.

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#### Conflicts of interest

None.

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