Discussion Kernel

Need for comprehensive standardization strategies for marketed Ayurveda formulations

Vishvanath Narhari Vaidya a, A.U. Tatiya a, Ashwini Elango b, Subrahmanya Kumar Kukkupuni b, Chethala N. Vishnuprasad b, *

a R. C. Patel Institute of Pharmaceutical Education and Research, Karwand Naka, Shirpur, Dhule, Maharashtra, India
b Centre for Ayurveda Biology and Holistic Nutrition, The University of Trans-Disciplinary Health Sciences and Technology (TDU), Bengaluru, Karnataka, India

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 (Dravyagunashas-thra), 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].
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 anemia, 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

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

**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 for Visual Inspection | Lod A | Lod B | Lod C | Lod D | Lod E | Lod F |
|---------------------------------|-------|-------|-------|-------|-------|-------|
| Form | Liquid | Free flowing | Transparent, free flowing | Free flowing, like water | Free flowing, thick | Free flowing, thick |
| 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; slightly turbid | No suspended particles but froth is seen | Floating particles, turbid |

| Attributes for Odour Inspection | Lod A | Lod B | Lod C | Lod D | Lod E | Lod F |
|---------------------------------|-------|-------|-------|-------|-------|-------|
| Type | Pleasantness and gross nature | Pleasant, sweet & sour odour | Not pleasant, sweet odour | Sweet odour | Appealing & sweet odour | Sweet odour | Unpleasant odour |
| Alcohol | Alcoholic | Alcoholic | Not alcoholic | Herbaeus | Slightly alcoholic | Moderately alcoholic | Slightly alcoholic |
| Herbaeus | Odour | Herbaeus | Herbaeus | Slightly Herbaeus | Slightly Herbaeus | Slightly Herbaeus |

| Attributes for Tactile inspection | Lod A | Lod B | Lod C | Lod D | Lod E | Lod F |
|---------------------------------|-------|-------|-------|-------|-------|-------|
| Form | Liquid | All samples are free flowing, non sticky and non-viscous liquids | All samples are free flowing, non sticky and non-viscous liquids | All samples are free flowing, non sticky and non-viscous liquids | All samples are free flowing, non sticky and non-viscous liquids | All samples are free flowing, non sticky and non-viscous liquids |

| Attributes for Taste | Lod A | Lod B | Lod C | Lod D | Lod E | Lod F |
|---------------------|-------|-------|-------|-------|-------|-------|
| Feel | Sharp | Moderate | Sharp | Sharp | Very Sharp | Very Sharp |
| Taste | Bitter | Predominantly sweet and slightly sour | Predominantly bitter and slightly sour | Predominantly bitter and slightly sour | Predominantly bitter and slightly sour | Predominantly bitter and slightly sour |
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, genuinely 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 pharmacopeial 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 physiochemical 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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