



## Research Article

### **DEPLETION OF GENUINE RAW DRUGS: A RISING THREAT IN AYURVEDIC DRUG MANUFACTURING INDUSTRY**

Maneesh T <sup>1\*</sup>, G Jai <sup>2</sup>, Rajmohan V <sup>3</sup>

<sup>1</sup>PG Scholar, Department of Rasasastra and Bhaishajya kalpana, Govt. Ayurveda College, Thiruvananthapuram, India

<sup>2</sup>Professor and HOD, Department of Rasasastra and Bhaishajya kalpana, Govt. Ayurveda College, Tripunithura, India

<sup>3</sup>Associate Professor, Department of Rasasastra and Bhaishajya kalpana, Govt. Ayurveda College, Kannur, India

\*Corresponding Author Email: drmaneeshts@gmail.com

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#### **ABSTRACT**

The last decade witnessed an accelerated increase of the global acceptance of traditional medicines and herbal products. But unfortunately there is no organized cultivation of the medicinal plants and most of the precious species are facing the threat of destructive harvesting. Majority of the manufacturers are thus forced to substitute or avoid the unavailable ingredients thus hindering the quality and safety of the marketed products. For analysing this scenario an in depth study was undertaken taking drugs of Dasamoola group as a representative of raw drug category facing huge consumption. The study intended to document the current availability status of Dasamoola drugs in the Kerala Ayurveda drug manufacturing industry and the measures adopted by the industry to overcome the scarcity of these drugs through a Cross sectional survey. Result of the study points out that over usage, destructive harvesting and lack of cultivation have alarmingly reduced the availability of Dasamoola group drugs in Kerala pharmacies. It has also documented the substitution of these drugs by the pharmacies and data regarding the adulteration faced by them. Thus this study invites an attention on the urgent need of judicious usage, cultivation and strict government regulations for such medicinal plants like Dasamoola which has high global demand.

**Key words:** Dasamoola, Raw drugs, Ayurveda drug manufacturing industry, Substitution

#### **INTRODUCTION**

International trade in medicinal plants and their products was 60 billion US dollar in the year 2000, with average annual growth rate of 7% and was expected to reach 5 trillion US dollar by 2050<sup>1</sup>. Owing to the increase in a global consumer preference towards herbal medicine and natural products, worldwide there is a growing demand for Ayurveda and other traditional forms of medicine. Besides the medicinal values pharmaceuticals, herbal food supplements, toiletries and cosmetics are also demanding medicinal plants in enormous quantity in the international market<sup>2</sup>. The majority of plants used in Ayurveda are procured from the wild, though around 10% are cultivated in private lands<sup>3</sup>. As per the annual report of AYUSH as on 01-04-2017 there are 9038 Ayurveda drug manufacturing units (licensed pharmacies) in the country<sup>4</sup>. The Ayurvedic manufacturing units have production of classical Ayurvedic drugs ranging from pure herbal to herbo-mineral medicine and also new dosage forms like capsules, tablets, syrups etc. Introduction of patent and proprietary medicines have made this system more user friendly and thereby Ayurveda easily acquired a wide acceptance. Rapid development of Ayurveda drug manufacturing sector has produced a huge shortage in commonly used medicinal plants. Approximately 90% of the medicinal plants used by the industries are collected from the forests and about 70% of the plant collections involve destructive harvesting due to utilization of roots, bark, wood, stem and the whole plant<sup>5</sup> which in turn causes threat to genetic stocks and diversity of medicinal plants. Most of the manufacturers have been facing substitution or adulteration of raw drugs, sometimes resulting in the avoidance of non available drugs, thus hindering the quality and safety of the marketed products. As the Quality, Safety and Efficacy studies are needed for obtaining approval for using Ayurveda drugs as medicines in

most of the foreign countries, these practices directly hits the exporting value. Thus the Indian manufacturers prefer to sell their products as dietary supplements without any health claims as it does not require any scientific evidence<sup>6</sup>.

Over utilization and habitat destruction have made many of the rare species in the endangered list. For analysing the status of such scarce drugs, Dasamoola<sup>7</sup> group drugs were selected which represents the raw drug category facing huge consumption. Dasamoola is a group of ten medicinal plants with root as the useful part and are widely used in therapeutics (Table 1). This group is a combination of five roots of herbs/shrubs (laghu panchamoola<sup>8</sup>) and root of five trees (brihath panchamoola<sup>9</sup>).

Dasamoola is a Constituent of most demanding formulations like Dasamoolarishta<sup>10</sup>, Chyavanaprasa<sup>11</sup>, Dhanwantharam taila<sup>12</sup> etc. The main reason for the scarcity of Dasamoola drugs are destructive harvesting for roots, inadequate cultivation and over usage. Being a part of most of the Ayurvedic products, it has a demand above 200 tons annually<sup>13</sup> and this bulk usage of valuable plants for numerous formulations might be an important contributory factor for including 3 of them in IUCN Red list.

In India, Kerala has the second largest number of Ayurvedic manufacturing units (753 GMP certified Ayurveda pharmacies) as on 01-04-2017<sup>4</sup> with massive raw drug consumption. So here the study intended to document the current availability status of Dasamoola drugs in the Kerala Ayurveda drug manufacturing industry and its impact along with the measures adopted by the Industry to overcome the scarcity of these drugs.

## Dasamoola in IUCN Red list

The IUCN (International Union for Conservation of Nature) Red List Categories and Criteria are intended to be an easily and widely understood system for classifying species at high risk of global extinction. A total of 560 plant species of India have been included in the International Union for Conservation of Nature and Natural Resources (IUCN) Red List<sup>14</sup>. Foundation for Revitalization of Local Health Traditions -Environmental Information System (FRLHT-ENVIS) has introduced databases on 195 red listed medicinal plant species in India<sup>15</sup> and 22 Red listed Medicinal plants in Kerala habitat were declared by State medicinal Plant Board, Kerala<sup>16</sup>. Both the list includes three medicinal plants of Dasamoola group.

## METHODOLOGY

To identify the depth of scarcity of Dasamoola faced by the Ayurveda drug manufacturing industry and their current management cross sectional survey was conducted among the selected pharmacies in Kerala. About 80% of the Ayurvedic raw drug market in Kerala was constituted by some major pharmacies which come about 2% of total manufacturing units<sup>19</sup>. So the well established major Ayurvedic manufactures in Kerala with maximum production, and thereby maximum raw drug consumption were selected as the study population. This study was approved by institutional ethical committee (IEC No. AVC IEC 177/2016) and informed consent was signed by the participants of the survey. Questionnaire with open and closed ended questions were developed after a preliminary survey in the pharmacies. The data regarding the sources, availability and current management of scarce drugs were discussed with the Head of Research and Development and Raw drug handling section using questionnaire method. Availability of the plants, sources, and their substitution, possible adulteration were discussed and included in the study. The pharmacies having more than one production unit were considered as single as they were following centralized raw drug purchase. So a total of ten manufacturing units were surveyed and the observations were statistically analyzed and included in the study.

## RESULTS AND DISCUSSION

### Source of Dasamoola drugs in Kerala pharmacies

Major pharmacies in Kerala were depending mainly upon native sources of raw drugs until the last decade. But the increasing demand had forced them to collect the drugs from distant available sources (through drug vendors). Among Dasamoola drugs, Prisniparni (*Desmodium gangeticum* Linn), Salaparni (*Pseudarthria viscida* Linn.), Kasmari (*Gmelina arborea* Roxb.), Patala (*Steriospermum sauveolens* Roxb.) were collected mostly from the Kerala sources, but Gokshura is collected exclusively from the out of state sources. Drugs like Vilwa (*Aegle marmelos* Linn.), Agnimantha (*Clerodendrum phlomidis* Linn.), Brihathi (*Solanum indicum* Linn.) and Kandakari (*Solanum xanthocarpum* Schrad.&Wendl.) are collected from both inside and outside sources (Table 3).

The average percentage of consumption of Dasamoola drugs among the ten surveyed pharmacies from Outside state sources and Kerala sources were 55% and 45% respectively (Graph 1).

Common outside state source of Dasamoola drugs is Virudhnagar district of Tamilnadu, and the drugs are also collected from Nagercoil, Vellore, and Dindigal of Tamilnadu. Dasamoola plants from Kerala are collected mostly from Kozhinjampara and Attapady of Palakadu district.

Among the ten surveyed pharmacies, eight pharmacies were sourcing Dasamoola drugs through raw drug vendors and two were inviting tenders. There were no cultivation initiatives of Dasamoola drugs from pharmacies and the local collection from farmers was also negligible for the collection of Dasamoola drugs. The huge consumption of medicinal plants and their poor availability have forced the manufactures to source the Dasamoola drugs from out of state sources.

### Useful part as per API and AFI

According to AFI part I, root and stem bark of brihath panchamoola and whole plant of laghu panchamoola were listed as useful part under the formulations containing Dasamoola<sup>20</sup>. But in AFI part II, in many formulations roots alone was mentioned as the useful part of Dasamoola drugs<sup>21</sup>. In API part II, root and stem bark of brihath panchamoola and whole plant of laghu panchamoola were mentioned as the part to be use<sup>22</sup>. There exists confusion on the useful part of Dasamoola drugs and due to the reduced availability the manufactures were forced to use whatever that was available in the purchased sample.

### Availability of Dasamoola in Pharmacies

All the ten pharmacies included in the survey received Dasamoola drugs as per their need, but none of them were receiving genuine root samples. The samples they received were always a mixture of root, leaf and woody stem portions.

Agnimantha, Salaparni, Prisniparni, Brihathi and Kandakari were collected as whole plant whereas Vilwa, Dunduka, Kasmari and Patala were received as a mixture of root and stem. But all pharmacies were using fruit of Gokshura in their preparations instead of root. Six pharmacies reported that they were not receiving genuine Kandakari samples as per need.

Substitution with other useful part of the same plant is now most common in Ayurvedic drug industry and it is the primary indicator of the upcoming depletion of the drug sources. So the drug samples received are almost mixed with other useful parts of the drug. As each useful part of a drug possesses various chemical constituents and action their substitution needs proper pharmacological and analytical studies prior to the substitution. Such substitution of few drugs like Vilwa<sup>23</sup>, Syonaka<sup>24</sup>, Agnimantha<sup>25</sup>, Gokshura<sup>26</sup> were already proven as effective in some aspects of pharmacological evaluation but the quantity of the substitute when other useful part of the same plant is added needs to be evaluated by conducting detailed pharmacological studies.

### Substitution and Adulteration in Dasamoola drugs

Among Dasamoola drugs in AFI, substitute was mentioned only for Agnimantha but all the pharmacies were forced for more substitution due to the unavailability of required drugs. In Kerala, instead of *Uraria picta* (Jacq.)DC, *Desmodium gangeticum* Linn. is used for Prisniparni and *Pseudarthria viscida* Linn. for Salaparni<sup>27</sup>. Gambhari (*Gmelina arborea* Roxb.) was usually substituted with the available *Gmelina asiatica* Linn. Six pharmacies were substituting Kandakari (*Solanum xanthocarpum* Schrad.&Wendl.) with Bhadra (*Aerva lanata* Linn.) in formulations containing Dasamoola group. This happened due to the reduced availability of Kandakari in the market and the pharmacies choose Bhadra as a better substitute than the *Solanum melongena* Linn. supplied by the drug vendors, considering the similar systemic actions of both drugs.

**Table 1: List of drugs in Dasamoola group**

Sl.No.	Sub Groups	Plant Name	Botanical Name
1	Brihath Panchamoola	Vilwa	<i>Aegle marmelos</i> Linn.
2		Agnimantha	<i>Clerodendrum phlomidis</i> Linn.
3		Dunduka	<i>Oroxylum indicum</i> Linn.
4		Patala	<i>Steriospermum sauveolens</i> Roxb.
5		Kashmari	<i>Gmelina arborea</i> Roxb.
6	Laghu Panchamoola	Gokshura	<i>Tribulus terrestris</i> Linn.
7		Brihathi	<i>Solanum indicum</i> Linn.
8		Kandakari	<i>Solanum xanthocarpum</i> Schrad.&Wendl.
9		Prisniparni	<i>Desmodium gangenticum</i> Linn.
10		Salaparni	<i>Pseudarthria viscida</i> Linn.

**Table 2: Dasamoola in IUCN Red list**

Sl.No	Taxon	Red list category
1	Vilwa ( <i>Aegle marmelos</i> Linn.)	Vulnerable <sup>17</sup>
2	Dunduka ( <i>Oroxylum indicum</i> Linn.)	Vulnerable
3	Salaparni ( <i>Pseudarthria viscida</i> Linn.)	Near threatened <sup>18</sup>

**Table 3: Source of Dasamoola drugs**

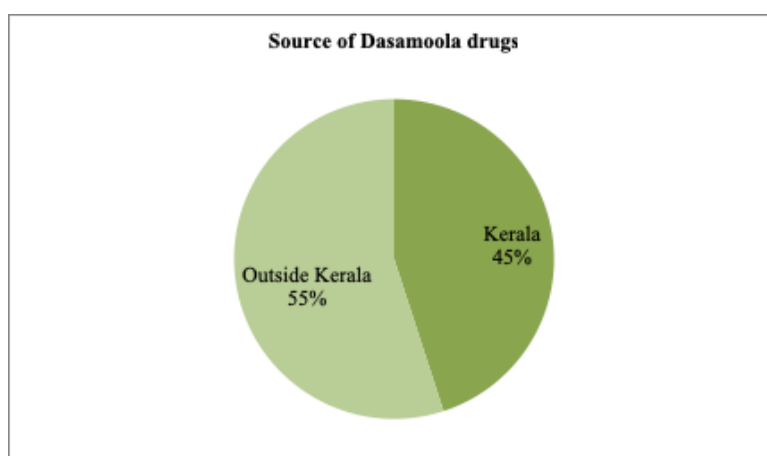
Kerala	Outside Kerala	Both sources
1. Prisniparni 2. Salaparni 3. Kasmari 4. Patala	Gokshura	1. Vilwa 2. Agnimantha 3. Brihathi 4. Kandakari 5. Dunduka

**Table 4: Substitutions of Dasamoola in Kerala pharmacies**

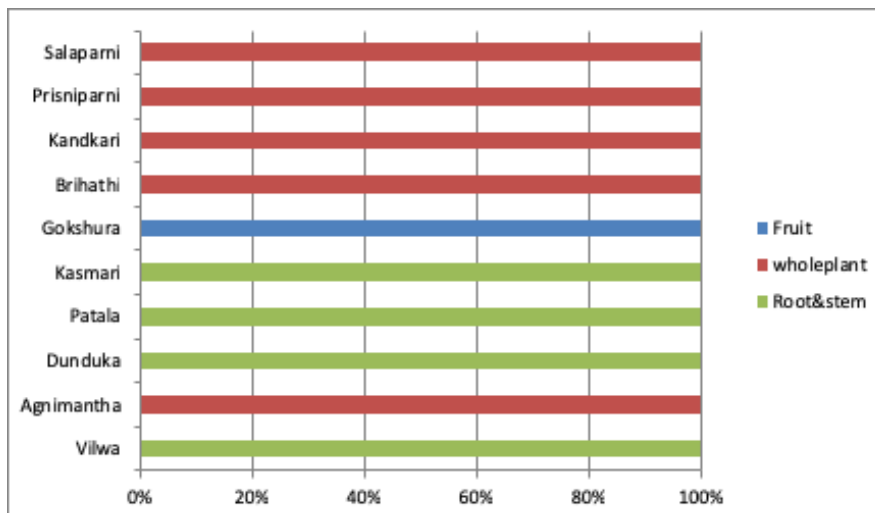
Drug	Source plant acc. to API	Substitution in Kerala pharmacies
Agnimantha	<i>Clerodendrum phlomidis</i> Linn.	<i>Premna corymbosa</i> Rottl.
Salaparni	<i>Desmodium gangenticum</i> Linn.	<i>Pseudarthria viscida</i> Linn.
Prisniparni	<i>Uraria picta</i> (Jacq.)DC.	<i>Desmodium gangenticum</i> Linn.
Kandakari	<i>Solanum xanthocarpum</i> Schrad.&Wendl.	<i>Aerva lanata</i> Linn.
Gambhari	<i>Gmelina arborea</i> Roxb.	<i>Gmelina asiatica</i> Linn.

**Table 5: Adulterants of Dasamoola in Kerala pharmacies**

Drug	Source plant	Adulterant received in Kerala pharmacies
Vilwa	<i>Aegle marmelos</i> Linn.	a. <i>Naringi crenulata</i> Roxb. b. Kattunaraka ( <i>Limonia acidissima</i> Linn.)
Syonaka	<i>Oroxylum indicum</i> Linn.	Aralu ( <i>Ailanthus excelsa</i> Roxb.)
Kandakari	<i>Solanum xanthocarpum</i> Schrad.&Wendl.	<i>Solanum melongena</i> Linn.
Gokshura	<i>Tribulus terrestris</i> Linn.	a. Earthen impurities b. <i>Acanthospermum hispidum</i> DC
Patala	<i>Steriospermum sauveolens</i> Roxb.	<i>Radermachera xylocarpa</i> Roxb.
Gambhari	<i>Gmelina arborea</i> Roxb.	<i>Trewia nudiflora</i> Linn.



**Graph 1: Source of Dasamoola drugs in Kerala Pharmacies**



Graph 2: Dasamoola-Available useful part in Pharmacies

Due to the raw drug scarcity Dasamoola drugs were received in adulterated form in the industry. Raw drug scarcity was the main reason for such practices and that can be identified only by experience and through close observation of analytical parameters. Well established quality control wing in the pharmacies can avoid such situations by adopting proper quality control parameters of the sample.

The samples of Vilwa were frequently adulterated with *Naringi crenulata* Roxb. and *Limonia acidissima* Linn., of Rutaceae family. The availability of *Oroxylum indicum* Linn. was very much reduced and most of the market samples received was of Aralu (*Ailanthus excelsa* Roxb.). In Ayurvedic literature there happens to be a controversy between *Ailanthus excelsa* Roxb. and *Oroxylum indicum* Linn. that both mentioned in the same name Syonaka<sup>28</sup>. In Bhavaprakasa nighantu, Aralu (*Ailanthus excelsa* Roxb.) is mentioned as a synonym of Syonaka<sup>29</sup>. Due to the decreased availability of Kandakari most of the raw drug dealers supplies edible brinjal (*Solanum melongena* Linn.) and sometimes wild varieties. Samples of Gokshura were adulterated mostly with fruits of *Acanthospermum hispidum* DC. Earthen impurities were usually found to be mixed along with Gokshura fruits. The samples received for Patala were not easily distinguishable with *Radermachera xylocarpa* Roxb. samples since both have similar external morphological characters. Similarly the samples of *Trewia nudiflora* Linn. were also frequently mislead as Gambhari due to their similarity in morphological characters.

## CONCLUSION

The global consumption of medicinal plants for herbal medicine, cosmetics and nutraceuticals has created a significant decline in the availability of valuable medicinal species. This directly affects the quality and efficacy of the herbal products and the same has reflected in the Dasamoola group drugs. Over usage, destructive harvesting and lack of cultivation have reduced the availability of Dasamoola in Kerala pharmacies. Since genuine root samples were not at all available in any of the surveyed pharmacies, the pharmacies were overcoming the situation mainly by substituting the drugs with available other useful parts. Agnimantha (*Clerodendrum phlomidis* Linn.), Salaparni (*Desmodium gangeticum* Linn.), Prisiniparni (*Uraria picta* (Jacq.)DC), Kandakari (*Solanum xanthocarpum* Schrad.&Wendl.) and Gambhari (*Gmelina arborea* Roxb.) were undergoing substitution by other plants. Practices of adulterations were also reported to be increasing in Vilwa (*Aegle marmelos*

Linn.), Syonaka (*Oroxylum indicum* Linn.), Kandakari (*Solanum xanthocarpum* Schrad.&Wendl.), Gokshura (*Tribulus terrestris* Linn.), Patala (*Steriospermum sauveolens* Roxb.) and Gambhari (*Gmelina arborea* Roxb.). Being an unavoidable group with wide spectrum of uses, their substitutions should be judicial and authorized after conducting detailed scientific evaluation studies. Substitution with other useful part is one of the early sign of the upcoming extinction. Therefore judicious usage and cultivation should be initiated for common medicinal species having huge consumption. Government aided supply of raw materials, proper implementation of Good Agriculture and Collection Practices (GACP), and strict regulations on medicinal plant consumption will be helpful to overcome the situation.

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