

## STANDARDISATION OF SIDDHA DRUGS

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**ABSTRACT:** *Siddha system is the ancient Dravidian system of medicine presently practiced predominantly in South India. In practice, generally the plants used are often in the compound form to which either herbs, metals, minerals and animals products are added. This paper attempts to describe the need for standardizing the drugs since the efficacy of medicines depends on their genuineness, indicating the methodology to be adopted for standardization.*

### INTRODUCTION

Drug is a substance used as a medicine. They are used in their raw state directly or after they are undergone some processes or modifications. It may be of plant or animal or metal and mineral origin<sup>1-4</sup>. Ancient physicians prepared medicines by themselves for the use of their patients. These physicians were well experienced in identifying the herbs and in the processes of preparing medicines. They were at liberty to modify the composition of any formula depending on the need and availability of raw materials. In course of time, variation in composition became an established practice, though the names of the formulations remained the same.

Conclusion about the efficacy of the medicine was drawn based on the actual clinical experience of a physician in a particular region. The drugs which were identified with one name have been equated with others under the same name. All these factors led to uncertainty about the identify and in used of drugs.

WHO has also recently recognized the inevitability of the use of alternate system of

medicine for certain conditions such as cancer, skin diseases, multiple sclerosis, etc for which no definite solutions are available in allopathic system<sup>5</sup>. For the acceptance of these drugs, a minimum level of quality control is required. But when the question of bulk production, marketing and distribution to the public arises, to ensure uniformity, quality control becomes an imperative need. To achieve this object and its effective enforcement, a guide book of standard known as 'Pharmacopoeia' is to be commonly followed by all manufactures. This warrants evolution of 'Siddha Pharmacopoeial Standards'. Hence the need for standardization includes study from birth of the plant to clinical application which involves various disciplines.

### Current status of standardization

The measurement of standards for drugs is an important criteria. The modern medicine industry uses standard raw materials and standardized production procedures. For example, aspirin or solol is prepared from salicylic acid by simple acetylation procedures<sup>6</sup>. Anti-malarial drug, quinine

and its salts are isolated from cinchona bark – *Cinchona officinalis* by a specific procedure. Many such preparations are made from a few simple chemicals. Thus, there is uniformity in quality from batch to batch, since both the ingredients and the method of production are standardized ones. Further analyzing them, gives accurate and reproducible results. For those drugs rigid standards could be fixed so that even a slight variation from the expected value could be attributed to sub-standard drugs or commercial exploitations. Modern sophisticated instrumentation techniques are employed for analysis to produce accurate results using a very little sample expended. Traditional medicines become more popular throughout the world in these days probably because of its least toxicity. Since the system involves the use of several plant drugs, the chances of adulteration and substitution are more, the latest techniques should be employed for the evolution of standards.

### **Methodology**

Standardization methodology can be classified as follows:

1. Collection / Procurement of raw drugs
2. Systematic identification
3. Method of purification/detoxication
4. Methods of manufacture
5. Finished produce standardization
6. Period of preparation
7. Preservation
8. Shelf life

### **Collection / Production of raw drugs**

The siddha texts specify that the herbs should be grown in fertile and congenial land, health, unaffected by injury or predators. It also states that the herbs grown in barren land, burial ground, marshy places, and sand dunes, food path, eaten by moth/termites, affected by forest fires, shrunken in severe cold are not suitable for medicinal purposes<sup>4</sup>. In practice, unfortunately these preconditions are not maintained for so many reasons. Several other important factors like age, habitats of a plant, variation in time and altitude of collection and post harvest conditions do alter the active chemicals qualitatively and quantitatively. The bioactive chemicals present in the plants are generally secondary metabolites, the physiological activities of which have rendered the herbs important as potent drugs and for related uses. The biosynthesis of these secondary metabolites, through genetically controlled, is affected strongly by environmental influences. As a result of the change in their concentration and quantities occurs. *Cinchona*, *Cephaelis*, *Atropa* and *Hyoscyamus* prefer medium range of elevations, whereas plants like *Rauwolfia*, *Catharanthus*, *Datura*, *Dioscorea* prefer lower elevations for better growth. In *Datura* and *Catharanthus*, the active principle content was maximum in plants at higher elevations<sup>7</sup>.

Suppliers of herbal drugs are generally ignorant about the type of quality requirements of raw drugs. The manufactures of herbal medicines also depend almost exclusively on the integrity of the herb suppliers. Therefore, knowledge and practice of ethnobotany for locating medicinal herbs are an advantage in this area. Organized collections, providing incentives to cultivator of herbs and establishment of herbal gardens by

manufactures of herbal remedies are some solutions to this problem.

### Systematic identification

Plant systematic and anatomical part have very significant role in the case of plants and plant products in ISM. For example different plants go under one name. Different plants/plant products belonging to different genera and families are given only one name. For kungliyam/sal – the resin of *Shorea robusta*, *Vateria indica* and *Salmalia malabarica* are offered. For Kostum/Kushtha-rhizome of *Costrus speciosus* (Zingiberaceae) roots of *Saussurea lappa* (compositae) and sometimes entirely different Malabar variety *Coffea travancoransis* (Rubiaceae) are available in the market. For cirunakappoo – flower buds of *Cinnamomum wightii* (Lauraceae) and *Musea fera* (Guttiferae), for tailcam birmi leaves of *Taxus baccata* (Taxaceae) and *Flacourtia cataphracta* (Flacourtiaceae), for vallarai / brahmi – *Centella asiaticai* (Apiaceae) and *Bacopa monnieri* (Scrophulariaceae), Mookiratai / punarnava – *Boerhaavia diffusa* (Nyctaginaceae) and *Trianthema portulacastrum* (Aizoceae), for Musti / talamulika – *Curculige orchiods* (Amaryllidaceae), *Murdannia scapiflorum* (Cammelionaceae) and *Asparagus adscendens* (Liliaceae) are sold in the market<sup>8</sup>. Therefore, it is essential that the raw drugs should be botanically identified.

Not only herbal drugs it is necessary that the drugs of mineral or zoological origin are also need to be correctly identified. For instance, the drug chinakkaram (alum) used by the ancient physician was potassium aluminum sulphate. The drug available in the market is ammonium aluminum sulphate which the supplier / manufacturer / user is

seldom aware. Similar is the case with gorोजना, the drug of animal origin<sup>9</sup>.

Of course substitutes are also officially accepted where ever possible e.g Maramanjil - *Coscinium fenestratum* (Menispermaceae) and *Berberis aristata* (Berberidaceae) are officially accepted, as both contain berberin as the major constituent, through the quantity might differ<sup>10</sup>. For Kattumalli – *Heracleum sprenglianum*, *H. rignes* and *H.concanense* can definitely be accepted as substitutes since both contain similar related coumarins though these could be easily differentiated through chemical examinations<sup>11,12</sup>.

For certain drugs, the trader adulterates with the inferior or substandard or similar drugs. Kattu jathikkai/kamuka – *Myristica malabarica* is used as an adulterant for Jathikkai/Jathipala - *M.fragrans*. Chemically they could be differentiated, as *M. malabarica* contains a group of ayrlpoly methylene ketones (malabaricones)<sup>13</sup> the presence of which could be detected by less than a milligram in *M.fragrans*<sup>14</sup>.

### Methods of purification and detoxification

Before entering into the process of preparation, the drug should undergo standard method of purification, whenever necessary, as there are more than on or two methods of purifications. For example, nabi/visha mushti – *Aconitum* sp. Though a poisonous drug used after mitigation gives better results if it is soaked in cow's milk than soaking in cow's urine. By this methods, the active principles lose their depressant action of the heart instead become stimulants having mild cardiotoxic property<sup>15</sup>.

Similar is the case with serankottai, tamiram (Copper), karuvangam (lead). Since the siddha texts prescribe more than one method for purifications, it needs standardization to have consistent results<sup>3,9</sup>. Karugangam after soaking it in nochi – *vitex negundo* juice has been found to contain more percent of lead. The purified drugs require analysis and should have standards to characterize.

### **Methods of Manufacture**

Process of preparation of formulation involves steps like powdering, heating, boiling, drying, grinding, calcinations, sublimation, filtration and so on. Each step requires proper and gentle way of handling so that the efficacy of the active constituents is not damaged. Classical literature describes different methods to prepare on compound medicine. In the preparation of certain categories of formulation such as tailams, decoctions, etc. the cause of high processing temperature, would result in the poor quality of the finished product. Since the efficacy of the medicines also depends on the nature of the wood used as fuel, specific wood to be employed in the process of preparation also needs examination<sup>16</sup>. Thus in the preparation also standardization textual procedure is to be followed so that uniform results are obtained for getting the reproducible standards.

### **Finished product standardization**

No doubt, standard ingredients processed through standardized production method would give standard finished products, but it is necessary to test the final product whether it corresponds to the standard uniformly. The product should be analysed for suitable parameters depending on the category of medicine.

Central Council for Research in Ayurveda and Siddha has provided proforma for each category of medicine<sup>17</sup>. For curnanam, loss on drying at 110<sup>0</sup>C, loss of ignition, water soluble ash acid insoluble ash, extractive values and gravity, saponification value, acid value, iodine value, volatile matter and pH. In the class of metal/mineral preparations such as basmam, centuram etc. qualitative and quantitative analysis of the respective inorganic ions should be carried out, depending upon the nature of the ingredients. In mercurial drugs the estimated value of mercury is taken as one of the parameters<sup>18,19</sup>.

Thin layer chromatography (tlc) is an important parameter which should be carried out in each class of preparations particularly of herbal origin<sup>20</sup>.

In herbo-mineral preparations like navauppu meluku, astaccuranam<sup>21</sup>, talakamattirai etc. qualitative analysis with respect to both organic and inorganic constituents were carried out to identify the presence of each ingredient. Further it is necessary that the major inorganic material or the active photochemicals should be quantitatively estimated, alongwith the tlc parameters.

For liquid preparations such as tinir, tiravakam etc. since water is an important ingredient, it should of good quality. The parameters prescribed for them are pH, specific gravity, total solid, refractive index and so on.

### **Biological standards**

The chemical parameters should be supplemented by biological standards, which can be carried out as follows.

- a. Pharmacology
- b. Biochemistry

### c. Microbiology

#### Limitations

Before concluding, certain limitations of the standardization which we come across also be put forth.

Few inorganic preparation, particularly of calcium group of basmas; muthupparapam, pravalapparpam and cankuparpam are used for various therapeutic conditions. Analytically, they are made up of calcium carbonate, with sulphate, chloride in traces. In all of them, the content of calcium is around 40% w/w<sup>18</sup>. No accepted method has been evolved to differentiate them. Since the cost of muthu (pearl), pavalam (coral), canku (conch shell) vary widely, one drug may be mistaken for other.

Tamiracenturam, analytically an oxide of copper is used for peptic ulcer. The preparation made by Siddha textual procedure alone can have the expected therapeutic effect than the synthetically constituted one. A manufacturer may prepare a synthetic product which will pass all the analytical tests in the lab, but will fail to give the expected therapeutic effect. Further work to differentiate them is required.

For preparations which involves the use of decoctions, it is mentioned to reduce the volume to 1/4<sup>th</sup> of the original volume. This measurement comes not as a whole number but as a fraction. Similarly, in prescribing plant juices, sufficient quantity is asked to be used in the preparation which will lead to variation of the bio-active principles. There should be a proper method to prepare the juices and fixed quantity should be added into the preparation.

In some of the preparation, the drugs are taken on the basis of number which results

in variation of active constituents. This should be changed to weight basis to have uniformity because the size of the individual piece is variable e.g nellikkai – *Embelica officinalis* is used as number in the preparation of certain medicines. Content of Vitamin C will definitely vary since it depends on the weight. The parameter can be made meaningful, by taking nellikkai / amalaki on weight basis.

In the preparation of (inorganic preparations) basmam, centurams, for calcination, certain number of cowdung cakes are asked to be used, which results in incomplete calcinations. Hence the number should be changed to weight basis.

#### Conclusions

1. The plants should be collected from the fertile land. Organised collection or cultivation of plants by the manufactures should be encouraged.
2. The drug requirement can also be met by the plant survey units and should be identified by the botanists.
3. The drug should undergo proper standard method of purification if necessary.
4. Herbarium of the plants must be maintained and should be periodically reviewed and updated.
5. Preparation should be made according to the formulae provided in the formulary published by Govt. of India.
6. The parameters for each category of medicine should be followed uniformly along with the thin layer chromatography and spectral data if necessary.

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7. Chemical parameters should be supplemented by biological standards.

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