

Basic Principles in Siddha Pharmaceutical Science- An Overview

Dr. Shyamala Rajkumar¹, G. S. Lekha²

¹Research Officer (Siddha), Central Council for Research in Siddha; Chennai

²Medical Consultant, Siddha Central Research Institute (SCRI), Chennai

Abstract: *Pharmaceutics in Siddha system of medicine is an important component with scientific background; the different aspects of this well developed discipline have been named as Gunapadam. As per the mode of application and medicinal forms, the pharmaceutical products in Siddha system have been classified into 32 internal and 32 external formulations. Basically the formulations are designed as per the concept of five elements and six tastes; employed the principles of synergism, antagonism and transformation into atomic or ionic form for the production of effective molecules. This manuscript highlights the GMP and guidelines exemplified in Siddha literature and address the scientific background of certain guidelines. One part of this article is devoted to discussion on influence of different factors in the expression of pharmacological activity of drug. Moreover this paper discusses the noteworthy endeavours in the standardization and commercialisation of Siddha formulations and contemplates the quality control sector of pharmaceuticals. The aim of this review article is to illustrate the scientific advancements in the ancient drug processing methods in Siddha system of medicine.*

Keywords: *Synergism, Antagonism, Transformation, Standardization and Commercialisation.*

I. Introduction

Siddha system of medicine is a complex system of science as it has included in the works of medicine, an extensive set of pharmacopoeia and Alchemy. Siddha system has applied its own fundamental principles in pharmaceuticals; various types of internal medicines and external therapies are in practice, with specialization in iatro-chemistry well before the development of modern science.

As per Siddha concept, human body is the replica of Universe; food and drugs irrespective of their origin are made of five basic elements namely, Earth, Water, Fire, Air and Ether.¹ The proportion of the elements present in the drugs vary and their preponderance or otherwise is responsible for their actions and therapeutic results.

According to basic Siddha concept the *Pancha bhootham* (five elements), *Arusuvai* (Six tastes) and *Uyirthatthu* (three humours) are interlinked. That is, predominance of fire and water element expresses salty taste, fire and air element expresses pungent taste, both are having hot potency, intake of them results in vitiation of *Azhal* humour. Similarly, the earth element with water element produces sweet tasted substance which can vitiate *Iyya* humour.² That's why the formulations are designed as per the fundamental principles of Siddha system.

The knowledge of plants and minerals from all the branches of science is used in preparation of medicine. In *Siddha* system chemistry had been found well developed into a science auxiliary to medicine. Moreover the knowledge in this system is not static and is inherently dynamic in nature and evolves in response to challenges posed by the environment. The practitioners of *Siddha* applies several procedures divided into processes such as calcinations, sublimation, distillation, fusion, separation, conjunction or combination, fermentation, purification, incineration of metals, liquefaction and extraction for the preparation of formulations.

II. Drugs In Siddha System

The source of Pharmaceutical preparations in *Siddha* system comprises *Thadhu* (Metals, Minerals & Arsenical compounds), *Thavara* (Herbs), and *Jeeva* (materials and products of Animal origin) elements.

Apart from the vast herbal sources, *Gunapadam- Materia Medica* describes the detailed classification of *Thadhu* drugs.

Kaelappa kaaramodu.....

..... *yirunoorodu yirupa thaache*

-Bohar Karasarathurai

The verse denotes the types of *Thadhu* drugs; They are, 11 types of Metals, 25 types *karasaram* i.e, different types of salts, 64 types of *Pashana* drugs that do not dissolve in water but emit vapours when put in fire, 120 *Uparasa* (mineral) drugs.³

The system has a classification of metals and alloys, which melts on heating and solidifies on cooling. These include gold, silver, copper, tin, lead and iron. These are incinerated by special processes and are used in medicine after purification or ore dressing. There is a group of drugs that exhibit sublimation on heating, which includes mercury and its different forms like red sulfide of mercury, mercuric chloride and red oxide of mercury etc. Sulphur, which is insoluble in water, finds a crucial place in *Siddha* Materia Medica along with mercury for usage in therapeutics and in maintenance of good health. In addition there are drugs obtained from animal sources like milk and milkproducts, conch, bones, teeth, bile, etc.

Eventhough the usage of *Thadhu* ingredients are more advanced in Siddha system, it was mentioned that the application of metallic preparations is preferred only after the use of herbal preparations. That was mentioned as,

*'Vaerpaaru thazhaipaaruru minjinakkal mella mella parpam chendhooram paaruru'*⁴

Siddhars applied the *Pancha bhoothic* principles in raw materials also, classified them as *Panchabhootha ulogam*, *Pancha bhootha uppu*, *Panchabhootha Pashanam*, *Panchabhootha uparasam*, and formulated the preparations according to the dominating *Pootham*, *Suvai* and *Veeriyam*.³ Basically the drugs are explained in five characteristics namely *Suvai* (taste), *Gunam* (quality), *Veeriyam* (potency), *Vibaham* (class) and *Ceykai* (action). The details regarding antagonistic- agonistic (*chathru-mithru*) compounds of drugs, dose, duration, season for ingestion, its compliance with geographical location and food restriction are well explicated in *Siddha* Materia Medica.

As per the key sorting in Siddha texts, based on their form, methods of preparation, shelf life, etc., 32 types of internal medicines and on account of modes of application 32 types of external medicines are being elucidated and practiced since years.³ Certain form of medicine, method of preparation and therapeutic procedures are elite and unique to Siddha system of medicine. Lakhs of formulations are available in Siddha Literatures; though a few are documented, countless are still in scripts and palm leaves, classical in nature.

III. Designing of Formulations In Siddha

The formulations, treatment methods in Siddha system are tailor-made and should be modified in accordance with the climate, habitat, body constitution and individual body conditions. Hence the quality control of the final product as well as standardization of drug is an exigent task of this system.

Siddha formulations are in natural form and contain in unison the active principles, inactive fibers, debris etc; they are not attempting to haul out the active principles and are disinclined to the concept of employing drugs as chemicals. This adds on additional value to these drugs by way of either neutralizing the toxic material if any or facilitating the excretion of unwanted chemicals by entrapping them with fibers, debris etc.⁵

The Inorganic substances occurring in nature have to be brought into atomic form for their effective usage as Medicine. The *Siddhars* developed the knowledge of transforming inorganic substances into atomic and ionic form, through organized processes, which can be easily absorbed in the system and results in highly efficacious product. The ideology behind the customized formulations which is being practiced in Siddha is the circumvention of side effects / after effects.⁵

Siddhars have followed various methods for medicinal preparations. Important among them are: 1. Process involving drugs based on combined ratio of five elements - *Aeaga mooligai prayogam* 2. Process involving Antagonism and Synergism – *Maarana prayogam* 3. Process involving distilled acids (*Dhravagam*) 4. Process involving *Ceyneer* and 5. Process involving *Muppu*.⁴

Uloga maaranam is the process for detoxification of metals and to increase the efficacy and potency of metallic compounds. Certain drugs are combined systematically and changed into liquid form known as *Ceyneer*. This *Ceyneer* helps to convert the drugs of combustible nature into non-combustible nature. The salt *Pooneeru*, the melted salt prepared from fuller's earth is converted into calcine powder form and used in *Muppu* processing.⁴

Preparation of specialized drugs like *Kattu*, *Urukku*, *Kalangu* and *Chunnam* which are having long shelf life and the medicinal forms - *Chatthu*, *Gurukuligai* of infinite life span, are being accomplished by these processing methods.

IV. Factors Affecting the Pharmacological Actions of Drug

The pharmaceutical procedures for any drug involve various steps starting from identification and collection of authentic raw material, application of standardized processing techniques for purification and formulation, packaging and storage of prepared drug, usage of adjuvant on application. In each step, the factors influencing and/or detaining the expression of pharmacological activity of drugs has to be considered.

The season of collection of raw drugs and geographical area of collection have great impact in the expression of pharmacological activity. According to Ancient Tamil Classics, the geographical areas (*Kurinji-*

Mountainous region, *Mullai*– Forest areas, *Marutham*- Cultivation area, *Neithal*- Sea shore and *Palai*- Desert area)⁶ have features that are ethnic to that area.⁷ Commonly the plants collected in *Marutham* and *Kurinji* area are highly nutritive and possess medicinal value; but the herb in other areas imbalances three humours and paves the way for certain pathological conditions.⁴

Genetic variants (at gene level) leading to the variability in the chemical composition of the population. Geographical, altitude, soil composition, microbial load/association, climate, temperature, season etc can cause fluctuation in the phytochemical ratio. A variation in the alkaloid composition in the leaves of *Adhatoda vasica* seasonally has been recorded. It is lowest in February and March and highest in the months of August, September and October. Similarly variation of alkaloid contents based on the age of the plant is reported in *Holarrhena antidysenterica*.⁸

The pharmaceutical processing of drug depends upon nature of the raw material- fresh or dry, solubility and heat stability of ingredients, route of administration and shelf life of drug, etc. Alteration in drug processing method is also having strong adverse impact on the formulations. The adverse effect of the drugs may be due of mis-processing. For example, while processing *Rasam*, if the impurities namely *Thodam/ Chattai* are not properly removed, it may leads to diseases like skin ailments, haemorrhoids, neurological ailments, respiratory ailments and seldom death also.³

The adjuvant or vehicle used along with the drugs may not be inert but *per se* may produce significant pharmacological activities. For example, usage of honey while treating anaemia supports the therapeutic efficacy of drug. This is due to the presence of minerals like Iron and vitamins like ascorbic acid in it.⁹ Most of the adjuvants enhance the activity of drugs, some of them neutralizes the toxic reactions, balances the humour, etc.

Hence while making changes in the classical formulation the impact factors should be noted; the modification in classical formulations (form, ingredients, adjuvant, etc) should not be made without any valid reason or supporting information.

V. GMP In Siddha Literature

The techniques and instruments used for the preparation of Siddha drugs are clearly explained in the literature. Raw materials used in the manufacture of drugs should be authentic, of prescribed quality and free from contamination. The impurities (*Thodam*) in each of the drug, methods for the purification of drugs are exemplified in classical texts. The principles regarding the collection of raw drugs (Eg: Collection of root of plant directed towards North (*Vadakku ver*)¹⁰ drug collection in the morning, etc), purification, preparatory procedures, etc should be followed.

1. Standards with Instruments of Drug processing:

Kalvam (stone mortar) is being used for grinding drugs in Siddha pharmacy. As per the classical, black coloured stone mortar is the better one for grinding process. This type of mortar will not release particles and thus the medicines may be obtained without impurities.¹¹ On the other hand, using of yellow or white coloured mortar results in demolition of the activity of drug and ends with inactive substance.³

Karandi (Spoon) is being used for scrapping the medicines from *Kalvam*, stirring or mixing of ingredients while processing, of this steel/silver spoon is *utthamam* i.e, Good, Wood/Horny material spoon is *matthimam* i.e, moderate; As Iron is the rusting natured material, usage of Iron spoon may reduce the effectiveness of drug.³ The ladle made of coconut shell (*akappai*) should be used in the preparation of Oils and Ghees; churning sticks for churning, spatula for the preparation of *elagam*. The ladle made of Iron should not be used for preparing perfumed oils, medicated ghee, lime juice and decoction made of milk, butter milk, etc. This should not be used in mercurial, arsenical and toxic herbal preparations also, because of demineralisation of Iron on exposure to such chemicals.⁴

Mud pot being used for the preparation of decoction or distillation process is made by using astringent and sour materials. In cases of sublimation, vapourizing, *mezhu* processing, etc. the mouth of the processing vessel should be narrow; for roasting process, the mud vessel used should be of shallow surface with brim and the vessel for decoction preparation should have a deep bottom. Meanwhile the vessels made of *Navaloga* (Nine metals) are not suitable for preparation of decoctions, medicinal ghee and for the distillation process. Further, the vessel used for the preparation of one medicated oil, should not be used for other oil processing, because, it not only spoils the medicine but also the health of the patient and the repute of the physician. In case of new pot, initially it should be prepared in such a way that ghee does not percolate further⁴.

Temperature for drug processing is also accomplished by various methods like *Pudam* – which can be classified according to the number / type of dung cakes, as *kaadai pudam*– using of single cow dung cake, *kavuthaari pudam* –3 cow dung cakes, *kukkudapudam* - 10 cow dung cakes, *varaaka pudam* –50 cow dung cakes, *Kejapudam*–1000 cow dung cakes, *manalmaraiyupudam*–90 cow dung cakes and *Bhoomi pudam* –using of sheep or goat dung of 4 fingers length and breadth size; based on the source of fire, the processes namely,

thanyapudam- keeping the drug immersed in grains, *umipudam* - keeping the drug immersed in husk/ chaff, *Pattaiyudam* – kept within Bark, *Sooriyapudam* - under Sunlight, *Chandra pudam*, *panipudam* and *paruvapudam*- processing of drugs under Moon, dews, and seasonal variations; burning of firewood in hearth, etc are in practice.³ In the processing of medicinal preparations the source of fire, type of fire, and method of exposure to heat is basically designed according to the nature of the drug material and the application of drug.

In *Pudam* processing method, the usage of naturally occurring dung material is vital. Dried cow dung cakes from forest is good for preparing medicine, dung of buffalos secondary, using of dung mixed with straw and dust will reduce the potency of drug. Based upon the necessity of temperature, calcium stones or sand or soil or ash can also be used in the processing of heavy metals or arsenical compounds like yellow orpiment, etc.³

While using firewood for *Thailam* processing, the type of fire (*Dheepakkini*, *Kamalakkini*, *Kathaliyakkini*, *Kaadakkini*) shall be decided as per the stage of processing; the type of firewood shall also be designed according to the ingredients of formulation. That is, the firewood of Neem, Coconut palm, Palmyra palm is apt one for mercurial preparations; Indian Arabic tree and Indian Kino tree is suitable for Iron containing preparations.³

On the other hand, the type of firewood shall also be designed as per the application of processing drug. That is, firewood of tanner's Cassia and country mallow is preferred for the processing of medicated oil for Fever like illness. Firewood of Indian jujube and Black Serrissa tree is ideal for the processing of Medicated oil for auricular, nasal and ophthalmic applications. Firewood of South Indian Mahua and Tamarind is applicable for the processing of external therapeutic oils. If the notified firewoods are unavailable, it shall be determined on the basis of the character or contents of the processing oil.¹²

Firewood of dead trees is of no use; firewood cut before three months is good and freshly cut wood will spoil the drug. *Pittha* would aggravate if the firewood of very old tree is used for medicinal preparations; if the bark is used, it may cause itching on application.⁴

2. Certain Guidelines in Drug processing:

While processing, the stages of drug should be assessed properly.

1. The preparations like *Utkali*, *Maathirai* should be in the non-sticky stage, i.e, the materials are not adhering to the fingers while finishing the product.³
2. The stages of the processing oil will be expressed on the surface as froth, the sediment on rolling by using fingers can roll like a thread without sticking between the fingers; sediment on exposure to fire burns vigorously without any crackling noise.¹²
Eventhough there is general expression of stages; concluding should be determined on account of application mode; oil processing shall be finished in three stages namely, soft stage (*Mirudupakam*), waxy stage (*Mezhugu pakam*) and gritty stage (*Karakarappu pakam*).i.e, medicated oil of *Mirudupakam* is for the internal application in *Vali* humour imbalance, medicated oil of *Mezhugu patham* is for external application and for *Azhal* diseases and medicated oil of *Karakarappu patham* is for application in the scalp and for *Iyya* diseases.¹²
3. As the effectiveness of drug depends upon the tiny or microscopic nature of the particles, the sieve of still finer mesh is mandatory in the processing of *chooranam*. The *chooranam* prepared by the use of mechanical devices like pulverizer should be allowed to cool down by way of spreading and then mixed well for storage and packing.¹²
4. As there is a chance of plenty of microbes inhabiting on *Choornam*, it should be subjected to the process of purification (*Choorana thooimai*) also. That is baking of *Chooranam* in suitable instrument and then process into fine powder.³
5. While processing preparations like *manappagu*, large spatula or ladle is used to stir-up continuously, otherwise it will deposit in the bottom and charring occur, this leads to burnt smell and bitter taste to the product.
6. Whilst processing *nei*, at certain stage of boiling froth will appear on the surface of processing ghee, at that moment the sediment should be analyzed by hands; if it is well processed the sediment shall be non-sticking, ghee is filtered off and preserved.¹²
7. In the processing of *elagam* (*Lehiyam*), honey should be added only after removing the processed drug from the oven and then mixed well into the *elagam* of suitable consistency.¹²
8. As the colour, characteristics and fineness of *parpam* is based on the quality of grinding process, it should be done in proper way. While processing, if there is any moisture content in the tablet (*villai*) material, the colour of the *parpam* may differ and hence proper drying is mandatory.¹²
9. In *Pudam* method of processing, the cake materials should be placed in earthen bowl properly i.e, there should be no gathering or one above the other; then only the temperature shall spread evenly. The size of the bowl depends on the quantity of material; bowl of over depth and breadth should be evaded.¹²

10. Place of reasonable air circulation should be selected for *pudam* processing, crater of defined breadth and depth is dug out in earth and the circumference is modulated by bricks to prevent the shed of soil, half of the defined cowdung cakes are being filled-up in the crater, earthen bowl containing the material is placed on that, remaining cowdung cakes spread on the said bowl and fired.¹²
11. Eventhough the cowdung cakes are the usual burning materials in *pudam* processing, some herbal barks or dung of Goats is being specified for the processing of certain drugs. Dung may also contain certain sand or waste materials, hence the number or quantity shall be modified as per the necessity of temperature in the process.¹²
12. Certain substances like *Ganthagam* (Sulphur), *Thalakam* (Yellow Orpiment) are insupportable to high temperature, and hence ash or sand is being used for calcination / *pudam* process. Herein suitable quantity of ash is spread on the bowl, the material in *villai* (tablet) form is placed on that, covered with ash and another bowl, smeared, pasted, dried and processed.¹²
13. The unfastening of setup is carried out only after the cool down of all materials.
14. Medicines once prepared should not be reheated. This principle applies for decoction, *elagam*, boiled juices, etc.⁴

3. Quality Assessment of Drug

Quality of drugs like *parpam*, *chendhooram* shall be assessed by the analysis of physical characteristics. Properly finished *parpam*, *chendhooram* is tasteless, so fine and smooth, devoid of shining or glittering nature. Whilst analyzing, scrapping of finished *parpam* or *chendhooram* in between thumb and index finger results in lodging of them into the ridges of the fingers, placing of a little amount on water shall show floating i.e, it will not sink. If it is blowed in fire, it will not rebound to the base element.¹²

The preparations like *chooranam* should be devoid of moisture content and tackiness. The particles of *chooranam* should be minute and be in short of binding with each other.¹¹

VI. Standardization of Siddha Drugs

Standardization of Siddha formulations is one of the mandatory requirements in order to develop quality drugs and also to conquer with adverse drug reactions on large scale production and marketing. The quality of the formulations are completely depended on the quality of the raw materials used and the quality of the drug indirectly signatures the quality of the processes. The raw materials such as herbs cultivated from different environmental and geographical conditions possess different types of chemical constituents. Hence harmonization of chemical constituents is complex in nature and therefore “finger-printing” profiles of phyto-constituents are the easiest and cost effective procedure to analyse raw drugs.

Also through the identification of chemical markers and their quantisation, the assay of the particular chemical constituent can be achieved and analytical reference standard can be prepared. The macroscopic, microscopic and physico-chemical parameters and aflotoxins are the routine tests in any quality control laboratories pertaining to herbal drugs. Nowadays, sophisticated analytical tandem techniques such LC-MS and GC-MS can be used to develop “molecular finger printing” and also NMR metabolic profiling is one of the best tools to the quantification of chemical markers without isolation. The volatile and low boiling chemical constituents can be identified and quantified through GC-MS and non-volatile constituents can be profiled through LC-MS.

The DNA finger printing methodologies can be effectively used for the raw materials of different origin. Finally the content of heavy metals is one the major task and can be achieved through elemental analysis techniques. The preparative HPLC techniques can be used to isolate major constituents and through lyophilisation processes the purest single molecule can be obtained and complete characterization of the molecule may help to identify the structure and it would enhance the possibility to study drug-drug interactions and to find out the mode of action of drugs.

While attempting to commercialize a product belonging to Siddha system, the issues regarding portability of the drug and shelf life of the drug arises, as most of the herbal medicines are in unsophisticated form, having short shelf life and the addition of preservatives for the purpose of marketing results in the reduced efficacy of the drug. Meanwhile, in the case of preparations like *parpam*, *chendooram*, *karuppu*, etc., there is no critical issue regarding the shelf life and portability, but the issue is regarding the adjuvant of the drug and the literal dosage of the drug, as most of these kinds of drugs are in nano-particulate form and the dosage should be in micro or milligram level, excess of which generates unwanted reactions, and the efficacy of the drug is more precise at that particular dose and whilst administering with particular adjuvant only.⁵

Modification in route of administration, modification in the form of drug for portability and palatability shows strong adverse impact in the activity of drug. Hence great research and development efforts are required to optimize the formulations.

VII. Conclusion

Pharmaceutics in Siddha system is essentially a personalized or customized scientific system; wherein the collection of raw materials, purification, processing should be done as per strict guidelines, principally based on experiential wisdom. Transformation of them into generalized and commercial system suffered greatly in quality assurance. Thus great research and development efforts are required to optimize the formulation aspects to ensure constant availability of standardized products with constancy of composition and efficacy.

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