

## STANDARDIZATION OF *Āyurvēdic* FORMULATIONS : A SCIENTIFIC REVIEW

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### ABSTRACT

Safety and efficacy of a drug mainly depends on the method of preparation. To assess the quality of a finished product, there should be some basic standards as well as methods of preparation. There are several parameters for testing the quality of a chemical drug, which have, are true indicators. So, there is no problem in assessing a synthetic drug's quality. As far as the preparation used in *Āyurvēdic* system of medicine, a drug formulation or design may not be a problem, because many formulations are well documented in classical texts. But, there is confusion with respect to standards to be followed while preparing a formulation as well as basic parameters to assess the quality of the finished product.

In *Āyurvēda*, *pañcavidhakaṣāyakaḷpana* are the basic pharmaceutical preparations, from which all the other preparations are developed. A specific method for each and every preparation and some basic standards of finished products are mentioned in *Āyurvēdic* texts to maintain their quality. This information may some times vary from text to text. To overcome this problem *Śārangdhara* mentioned detailed information about various formulations with respect to their methods of preparation as well as basic standards and are documented in *Śārangdhara Saṁhita*.

### Introduction

Standardization of indigenous herbal drugs is a vexing problem in most of the countries. Safety and efficacy of drugs depends on their quality. The quality can be achieved by standardization. There are several procedures for assessing the quality of a drug in modern science. The same methods are not much helpful in standardizing the *Āyurvēdic* drug because; the basic principles of the two sciences are different. So scientists

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are trying to develop better methods for standardizing the herbal drugs. In *Āyurvēda* standardization of formulations differs from text to text and different authors mentioned different methods for preparation of a formulation. Hence there is so much of confusion with respect to standards, parameters, to be followed while preparing the drugs and to assess the quality of finished products.

*Śārāṅgadhara*, author of *Śārāṅgadhara saṁhita* was son of *Dāmōdara*, whose period may be the early part of 14<sup>th</sup> century A. D. His classic is an important and popular Sanskrit medical work of medieval period, which can be inferred from its inclusion in the minor triad of authoritative works called *laghutrayee*. The changes in theory and practice of Indian medicine especially *Bhaiṣajyakalpana* reflects in it. The text is arranged in three sections (*Khaṇḍa*) and the last chapters of the first section deals with the basic principles of preparation of drugs. The second section (*madhyama khaṇḍa*) completely deals with pharmaceutics and *Rasasāstra* (Indian alchemy).

*Śārāṅgadhara*, stated that he himself has gone through the information available in the various classical texts of the period and tried to solve the confusions regarding standardization and mentioned the standard methods for preparation of various formulations and finished products like *snēhas*, *avalēha* etc. According to *Āyurvēda* all the preparations are developed on the basis of *pañcavidhakaṣāyākalpana*, which are the basic pharmaceutical preparations viz<sup>1,7</sup>.

1. *Swarasa* – Juice
2. *Kalka* – Paste/Bolus
3. *Kvātha* – Decoction
4. *Hima* – Cold infusion
5. *Phāṇṭa* – Hot infusion

These are the simple pharmaceutical preparations to be prepared instantly and used within 24 hours, as they cannot be stored for more than a day. Standard procedures are mentioned for these preparations but not specific standards for the finished products. Even though the finished products should have the basic standards like, the *rasa* – (taste),

*varṇa* (color) and *gandha* (odor) of the ingredients out of which the drug is prepared. The nature of the *pañcavidhakaṣāyakaḷpana* normally succeeding one is less in potency/ easily digestible than the preceding.

### Standard Methods of Preparations

#### Basic Preparations

##### I. *Swarasa* : (Fresh Juice)<sup>1,4</sup>

The juice extracted from a fresh green drug by pounding it and squeezing through cloth. If fresh drugs are not available, then the juice should be extracted from dry drugs by the following methods.

1. For normal dry drugs, 1 part of powder mixed in 2 parts of water should be kept over a period of a day and night and filtered. This liquid known as *uttama swarasa* (good juice).
2. In case of dry drugs, which are more *suṣka* (very dry) in nature, the juice extracted by boiling them in water 8 times of their quantity and reduced to a quarter.

The extraction of juice is difficult from the green drugs like *nimba* (neem) and dry drugs like *śuṅṭi* (dry ginger), hence juice may be extracted by a special method known as *puṭapāka*. In *puṭapāka* the drugs are pasted by adding water if necessary, and wrap the paste of the drugs with thick leaves like *vaṭa* (Banyan tree) etc., and smear mud 2 *angulas* thickness over it, put it into fire and remove when it becomes red-hot. The juices should be extracted by squeezing the cooked *kalka* through clothe.

##### II. *Kalka Kalpana* – Wet Paste / Bolus

A green or dry drug converted into a paste by pounding and triturating it on a stone with a little quantity of water if necessary, is called '*kalka*'.

### III. *Kvātha* – Decoction/Infusion

*Kvātha* prepared by boiling 1 *pala* (48gms) of *Yavakūṭa* (coarsely powdered into about 2mm in size) drug with 16 parts of water in an earthen pot over mild fire till the liquid is reduced to 1/8<sup>th</sup> of the original quantity. During the course of boiling the earthen pot should not be covered with a lid.

#### Other preparations<sup>2,3</sup>

1. *Yavāgu*: 4 *palas* (192 gms) of drug is to be boiled in 64 *palas* (3.072 kgs) of water till it reduced to half. In this preparation normally broken grains are to be added along with the drugs and a thick gruel prepared. This is called *Yavagu*.
2. *Yūṣa*: 1 *pala* (48gms) of drug with powders of *śuṅṭhi*, *pippali* each ½ *karṣa* (6gms) boiled in 1 *prastha* (768gms) of water is known as *Yusa*.
3. *Pānakalpa*: 1 *pala* (48gms) of drug boiled in 64 *palas* (3.072Kgs) of water and reduced it to half of the quantity is called *Pānīya jala*.
4. *Uṣṇōdaka*: Reducing of water to 1/8<sup>th</sup>, 1/4<sup>th</sup>, or ½ of its original quantity by boiling is known as *Uṣṇōdaka*.
5. *Kṣeerapāka*: 1 part of drug boiled in 8 parts of cow's milk + 32 parts of water and reduced to the quantity of milk is known as *kṣeerapāka*.

### IV. *Hima Kalpana* – Cold Infusion<sup>2,4</sup>

*Hima* is prepared by mixing 1 *pala* (48gms) of coarsely powdered drug with 8 *palas* (384gms) of cold/normal water and kept in a mud pot for one over night and filtering through cloth on next morning.

### V. *Phāṇṭa Kalpana* – Hot Infusion<sup>2,4</sup>

*Phāṇṭa* prepared by mixing 1 *pala* (48gms) of powdered drug with 1 *kuduva* (192gms) of hot water in a mud pot and filtering through cloth after some time. *Śārangdhara*, specifically described the *Mantha kalpana*, which is also a kind of *phāṇṭa*,

prepared by 1 *pala* (48gms) of powdered drug added to 4 *palas* (192gms) of cold water and churned well in a mud pot for some time to a thick consistence.

The other preparations like *cūrṇa* (Powders) *Vaṭies* (Tablets) *Snēhas* (Oil & Ghee) etc. are developed on the basis on these five standard method of preparations.

### I. *Cūrṇa Kalpa* – Powder<sup>2,4</sup>

The *cūrṇa* is prepared by nicely pounding the dry drugs and *Vastraḡālita* (sieving through clothe).

### II. *Guṭika Kalpa* – Pills<sup>3,5</sup>

The *Guṭika*, *Vaṭi*, *Mōdaka*, *Vaṭika*, *Pinḡi*, *Guḡa*, *Varthi* are synonyms. *Gutikas* are prepared by cooking or without cooking the powdered drugs with jaggery/sugar/*guggulu* or by macerating the powder with any liquid, honey and rolling it into pills.

1. Sugar to be added 4 times the quantity of powdered drugs.
2. *Guḡa* to be added double the quantity of powdered drugs.
3. *Guggulu* and honey to be added equal in quantity.
4. Water for maceration is to be twice the quantity powdered drug.
5. The rolled pills should be one *Karṣa* in weight.
6. They should be dried and in shade and preserved.

### III. *Avalehya Kalpana* – Confection<sup>3,5</sup>

The semi solid mass obtained by boiling the *kwātha* is known as *avalehya* or *lehya* or *rasakriya*.

1. If sugar is to be added, it should be 4 times.
2. If Jaggery is to be added, it should be double the quantity.
3. If any liquid is to be added, it should be 4 times.

***Avalehya siddhalakṣaṇa***

- a. Well prepared *avalēhya* should come out like a thread, when taken out with a rod, should sink in water, if pressed or rolled between fingers the impression of finger print should appear on it.
- b. Should have pleasant smell, good color and taste.

**IV. *Snēha Kalpa* – Medicated Ghee and Oils<sup>6</sup>**

Medicated ghee (clarified butter) or vegetable oils are to be prepared by mixing the proportionate paste of the drugs, decoction, ghee or oil and boiling together until they attain the *snēhapāka siddha lakṣaṇas* (characteristics of properly cooked *sneha*). The proportions are as follows

- 1 part of paste of drugs
- 4 parts of ghee or oil
- 16 parts of decoction of the drugs

***Snēhapāka siddhalakṣaṇas***

1. It should assume a wick like shape at the end of boiling if the *kalka dravya* rolled in between the fingers.
2. The *kalka dravya* should not produce any crackling noise if thrown on fire.
3. For oils, bubbles should appear at the end of the terminal stage of boiling.
4. For ghee, bubbles should disappear at the end of the terminal stage of boiling.
5. The finished *snēha dravya* should have good smell, color and taste

***Snēhapāka* – Boiling Or Cooking**

It is of 3 types

1. *Mṛdu pāka* (Mild cooking): If the *kalka* is pressed in between fingers, it should yield large quantity of *snēha*. *Mṛdupāka Snēha* is normally useful for *nasya karma*.

2. *Madhyama pāka* (Moderate / Medium cooking): If the *kalka dravya* does not yield any *snēha* and soft in consistence then the *pāka* is known as *Madhyama pāka*. *Madhyama pāka snēhas* are useful for all other purposes.
3. *Khara pāka* (Hard-boiling): The *kalka* does not yield any *snēha* and hard in nature, this type of *pāka* is said to be *Kharapāka*. *Kharapāka snēhas* useful only for *abhyanga* (external application).

#### **Abnormal Pāka**

1. Over boiling beyond *Kharapāka* results into *Dagdapāka*. *Dagdapāka snēhas* are not useful as they cause burning sensation.
2. If *snēha* is boiled less than to that of *Mṛdupāka*, which results into *āmapāka snēha*. It is not only ineffective but also causes indigestion.
3. Preparation of *grta*, *taila* should not be completed within one day. Because longer the duration of the preparation better the acquisition of properties of the drugs into them.

#### **Preparation of decoction: Used in the *snēha kalpa***

Generally for preparing decoction 1 part of drug should be boiled in 4 parts of water and allowed to reduce it to a quarter. Depending up on the nature of drug the proportion of water and raw drug varies.

1. If the drugs are soft in nature, the water should be 4 times of the quantity of the drugs.
2. If the drugs are medium or moderately hard in nature, the water should be 8 times of the quantity of the drugs.
3. If the drugs are very hard in nature, the quantity of water should be 16 times of the quantity of the drugs.

4. If the quantity of each drug varies from 1 *Karṣa* (12gms) to 1 *Pala* (48gms) the water should be 16 times of the quantity of the drugs.
5. If the quantity of each drug varies from *Pala* (48gms) to *Kuḍava* (192gms) the water should be 8 times.
6. If the quantity of each drug varies from *Prasta* (768gms) to *Khāri* (196.608Kgs), the water should be 4 times of the quantity of the drugs.

#### **Different opinions regarding the preparation of *Snēha***

1. If *Snēha* is to be prepared with only water, decoction, meat juice or fresh juice of herbs, then their quantity should be 4, 6 & 8 times of *kalka* (Paste of drugs) respectively.
2. If the *Snēha* is to be prepared with milk, curd, meat juice or buttermilk the *kalka* should be 1/8<sup>th</sup> part of sneha and water should be 4 times of it.
3. In the preparation of *Snēha*, if the *drava dravyas* are more than 5 in number, the quantity of *drava dravyas* should be equal to quantity of *snēha*.
4. If *Snēha* should be prepared by only drugs, *kalka* of the same drugs along with 4 times of water may be added to it.
5. In case of *Snēha* prepared by *kaṣaya* only, then the *Kvātha dravyas'* *kalka* may be used.
6. If *kalka* is not mentioned or should not be used in *snēhapaka* in such conditions *Snēha* should be prepared by *drava dravyas* only.
7. If in the *Snēha*, *puṣpa kalka* is mentioned, it should be added 1/8<sup>th</sup> quantity of *Snēha* and water should be 4 times of *Snēha*.

#### **V. *Sandhāna Kalpana* (Fermented Preparations) <sup>6</sup>**

Fermentation of Fresh Juice or decoction of herbs by adding Jaggery, Honey, candy sugar along with *Dhātaki* flower (woord *fordia fruticosa*) or *Madhūka* flowers (*Madhuca indica*) in closed vessel for stipulated time is known as *Sandhāna* (fermantation)



*kalpana*. There are different types of preparations like *āsava*, *ariṣṭa*, *Sura*, *Seethu*, *Vāruṇi* etc, are mentioned by Śārangdhara. But the *āsava* and *ariṣṭa* are commonly using in medical practice.

*Āsava Kalpana*: *āsava* is prepared by *drava dravyas* (liquids) without *boiling* drugs.

*Ariṣṭa Kalpana*: *Ariṣṭa* is prepared by using boiled *drava dravya* or *Kvātha* with the drugs.

If the proportion of ingredients not mentioned in the preparation of *Sandhāna Kalpana* the following proportions are advised.

1. 1 *Drōṇa* (12.288Kg) of *drava dravya*
2. 1 *Tula* (100 *palas* – 4.800Kg) of *Guda*
3. ½ *Tula* (50 *palas* –2.400Kg) of *Madhu*
4. 1/10<sup>th</sup> *Tula* (10 *palas* – 480gms) of *Praksepa drugs*

## Discussion

### The Scientific Validity -Views of Śārangdhara

1. *Puṭapāka svarasa kalpana*:
  - a. It is a method of extracting juice subjecting the drugs to indirect heating, in which the active principles will not affect.
  - b. When *svarasa* cannot be extracted from drugs such as *nimba* etc in which the water content is less. *Puṭapāka svarasa kalpana* is useful to extract the juice.
  - c. Certain disease conditions like *Atisāra*, *Raktapitta*, *Grahaṇa*, *Arśas* etc will have the *āma* /*Agnimāndhyata*. In that conditions *Puṭapāka* will bring *laghutva* (easily digestible) to the drugs, which facilitate absorption of the drugs to show their action.
2. *Kṣīrapāka* is mentioned for the drugs having properties of *Tikṣṇa*, *Kaṣāya rasa* etc., Even for decreasing the intensity of the drugs in certain disease

conditions like *Hṛdrōga*, *Vāta Vikāras* etc., *Kṣīrapāka* is advised. It is also palatable and nutritive to the patients.

3. *Pathya kalpanas* like *Yavāgu*, *Yūṣa*, *āhāra Kalpanas* etc. are having nutritive and medicinal values.
4. *Pāna kalpanas*(drinks) like *Uṣṇōdaka/Pāna/Pānīya* are indicated in conditions such as thirsty, dehydration and also to check the diseases.
5. *Phānta*, *Hima kalpana* are mentioned for the drugs to retain their active principles, which are in volatile nature and indicated in *Pitta*, *Rakta Vikāras* like *Tṛṣṇa*, *Dāha* etc. In this *kalpana* boiling of the ingredients in water for longer period like *kaṣaya* is not advised because it may affect the active principles and also not good for the disease, where it indicated.
6. In *Cūrṇa kalpana*, the *Cūrṇa* (powder) sieving through cloth may become finer than No. 80-mesh sieve (WHO 125). *Bhāvana*, *Mardana* with various liquids enhances the disintegration, action, concentration, absorption and assimilation of the drugs.
7. In *Vaṭīkalpana*, *bhāvana*, *mardana* with various liquids till it attain *gutikāpaka*, may enhances the binding, disintegration, action concentration, absorption, assimilation and self-life of the drugs. Drying the tables should be under shade, because exposing to sun may affect the drug.
8. *Snēhas*, *gutikas*, *avalehas* etc. should be prepared allowing prescribed time of preparation, otherwise the acquisition of properties and ingredients may affect.
9. *Avalēhya/Snēha siddhalakṣṇa* are important to maintain their quality, self-life and indicate the end point of the preparation. The preparation either before attaining end point or continuing beyond the end point may spoil the preparation.
10. For *Snēha kalpana*, *madhyamapāka* is always better in large-scale production because it can be used for several purposes.

### Conclusion

The standard method of preparation of Āyurvēdic formulations mentioned by *Śāraṅgadhara Saṁhita* is to be updated by adopting the G.M.P. specifications for manufacturing Āyurvēdic drugs on large scale without deviating from basic principles and standard methods, as they are having scientific validity till date.

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## सारांश

### आयुर्वेदीय औषधियों का मानकीकरण: वैज्ञानिक दृष्टिकोण

अला नारायण एवं वाराणसी सुभोस

औषधियों की सुरक्षा एवं कार्य क्षमता उसके घटक द्रव्यों तथा उसकी निर्माण पद्धति पर निर्भर है। किसी औषधि की गुणवत्ता निर्धारित करने के लिए एक विशिष्ट निर्माण पद्धति और मौलिक मानक आवश्यक है। आधुनिक कृत्रिम औषधियों की गुणवत्ता निर्धारित करने के लिए विविध परीक्षण है, इसलिए आधुनिक चिकित्सा शास्त्र में यह समस्या नहीं है। किन्तु आयुर्वेदीय चिकित्सा शास्त्र में यह एक जटिल समस्या है क्योंकि आयुर्वेदीय ग्रन्थों में विभिन्न प्रकार की औषधि निर्माण विधियाँ और मौलिक मानक वर्णित है।

आयुर्वेद की मूलभूत कल्पनाएँ पंचविध कषाय कल्पनाएँ हैं, इसी आधार पर अन्य कल्पनाएँ विकसित हुई हैं। प्रत्येक कल्पना की विशिष्ट निर्माण विधि और मौलिक मानक बताये गये हैं। किन्तु इस विषय पर आचार्यों के विविध मतान्तर है। इस समस्या के समाधान के लिए शार्ङ्गधर ने अपनी संहिता में प्रत्येक कल्पना की विशिष्ट निर्माण विधि और मौलिक मानकों को शास्त्रीय दृष्टिकोण से वर्णित किया है।