

**CLASSICAL REFERENCES ON STANDARDIZATION AND
VALIDATION OF AYURVEDIC DRUGS**

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ABSTRACT :

Traditional Medicine has a vital role in curing various diseases, 70% of world population depending on Traditional Medicine. To achieve better therapeutic values, the medicine should be properly identified, processed so that potent enough to cure the diseases. The increased demand of herbal medicine, people are using the substitutes and adulterants. So we need a help of standardization, in the text we find the reference with respect to the identification, seasonal collection of , synonyms, properties and some specific character of the drug. Sharangadhara gives a correct method of preparation and also the characters of prepared formulations. The standardization of the drug which is explained in the text and the standardizations parameters explained in the Ayurvedic Formulary of India are discussed.

Key words: Traditional Medicine, standardization.

INTRODUCTION :

Before 19th century people completely depend upon the traditional medicine. World Health Organization (WHO) defined Traditional Medicine as the sum total of the knowledge, skills, practice, based on the theories, beliefs and experiences of indigenous cultures whether explicable or not used in the maintenance of health the prevention, diagnosis, improvement and treatment of physical and mental illness.

Importance of Ayurvedic Medicines:

No satisfactory drugs available in modern pharmaceuticals for most of the degenerative disorder and also re-emerging resistant infections. Modern medicine is a single molecule with many side effects Ayurvedic medicines have many molecules, safe, can treat many diseases like degenerative disorder and prophylaxis for diabetes and cancer. Adjuvant cures the side effects as well as it enhances the efficacy of the drug.

Weakness / quality assurance :

The therapeutic quality/effect of medicinal plants are due to the presence of the biologically active chemicals which are mostly secondary metabolites such as alkaloids, glycosides, saponins, coumarins, flavonoids and terpenes.

Traditional Medicines (TM) is collected from wild areas, so sustained supply of quality raw materials is therefore difficult and variability with respect to morphological and chemical composition due to macro – micro environment, season, stage, growth and development of the plant.

In Ayurveda there is a protocol for collection of dravyas i.e.

Importance of Seasonal drug collection:

- Leaves to be collected in mature state because plants contain all the products of metabolism, so one can get a desired effect.
- Roots and rhizomes are collected during sarat because tissues are fully

matured and medicinal constituents are abundant in this season.

- The bark to be collected in sarat or early summer, because the cambium is active helps in the re growth of the stem

Method of drug collection¹

- Place of collection – herbs growing in north or east to be collected (moon and sun

are the gods of north and east direction) with respect and devotion towards nature.

- Plants to be collected on Pushya,Hastha,Mrigasira and Aswini naksatra , during these periods, plants contain highest amount of active principles
- Herbs growing on dirty places, marshy land, infected with worms, fire, snow should be discarded
- Time of collection – during sunshine

Table – 1 shows the seasonal collection of the dravyas according to different acharyas.²⁻⁶

Part used	Caraka	Susruta	Modern science
Mula (Roots)	Grishma or sisira (May-July)(Jan-Mar)	Pravrit (May - July)	Autumn or Spring or when leaves are fully grown and fruits are ripened
Patra (Leaves)	Varsa & vasanta (July-Sept)(Mar May)	Varsa (July – Sept)	Before the flower bloom
Sakha (Branches)	Varsa & vasanta (July-Sept)(Mar-May)	Varsa (July – Sept)	
Puspa (Flowers)	Seasonal		Time of blooming, half blooming or complete blooming
Phala (Fruits)	Seasonal	-	Mature fruits
Sara	Hemanta(Nov-Jan)	Vasanta,Mar-May	
Twak (Bark)	Sarat (Sep-Nov)	Sarat (Sep- Nov)	Prior to spring or after spring
Kanda	Hemanta (Nov-Jan)	Sarat(Sep-Nov)	
Ksira (Latex)	Sarat(Sep - Nov)	Hemant,Nov-Jan	

Table – 2 Collection of Jangama Dravyas⁷

Rakta, roma, nakha	Praudhavyas
Ksira,mutra,purisa	After digestion of food

Table – 3 Depending upon the Therapeutic usages⁸

Karma (Therapies)	Panchamahabhuta Adhikya	Rtu (month)
Vamana (Vomiting)	Agni + Akasha	Vasanta (Mar - May)
Virecana (Purgation)	Prithvi + Jala	Vasanta (Mar - May)
Vasti, Nasya (Medicated enemas and errhine therapy)	Prithvi + Jala	Sarat (Sep - Nov)

Ideal drug for the preparation of the formulations⁸ :

- Drug should have Many characters
- We can Prepare many formulations
- Ideal to administer

Need for standardization⁹:

- Correct taxonomic identification of medicinal plant.
- Study on the medicinal part: root, stem, bark, leaves, flowers, fruits, nuts, gum, resins, etc.
- Collection details: location, stage & development/growth of the plants, time, pre-processing if any, storage etc.
- Organoleptic examination of raw drug- Evaluation by means of sensory organs: touch, odor and taste
- Microscopic & molecular examination
- Chemical composition (TLC, GLC, HPLC and DNA fingerprinting of the plant.
- Identification of biologically active marker compound(s)
- Shelf life of raw drugs

Identification of dravyas as per Ayurveda (Raw drugs)¹³:

- Haritaki (*Terminalia Chebula*) identified by its characters like - Nava (new), Snigdha (moisture), Ghana (hard), Gola (round) ,Guru(heavy),Pancarakhee (5 ridges on fruit) Sinks in water¹⁰
- Candana (*santalus album*) identified by its Taste as – bitter , rubbing – it gives yellow in color, on breaking –

gives red in color by Appearance – white in color with Many nodes¹¹

- Guggulu (*commiphora mukul*)- Characteristic of New guggulu – Snigdha (oily) Swarna varna (golden yellow in color), Pakwajamboophala (red in color), Sugandha gandha (good smell), Picchila (slimy), Old - Suska (dry), Durgandha (bad smell) Varna heena (lost its normal color)¹²

- Kumkuma (*Crocus sativus*)- Kesara – sookshma ,Rakta varna(red color), Padma gandha (uttama),Ketaki gandha (madhyama),Madhu gandha (adhama)

Formulations- Principle:

Sharangadhara explains the siddha laxanas of the each preparation which shows the standardization in the ayurvedic formulation Ex – Taila siddha laxanas, avalehya siddha laxanas, choorna, asava siddha laxanas etc.

Standardization in Ayurveda (prepared formulations)

- Kalka - A *soft paste* is prepared with a fresh or dry drugs with and with and with adding the water.¹⁴
- Curna is a fine powder of completely dried drug/ drugs, which is *filtered through the cloth*.¹⁵
- Kwatha - The term kwatha has been derived from the word *kwathana* ie boiling¹⁶.

- Ushnodaka - The water obtained by boiling and reducing it to $1/8^{\text{th}}$, $1/4^{\text{th}}$, or $1/2$ **Just sufficiently**¹⁷

- Rasakriya - Rasakriya are **solidified decoctions** or swarasa of a drug or drugs¹⁸

- Test to know the onset of fermentation -**Floating of ingredients, Effervescence, Hissing sound, Mild sour taste, Mild alcoholic odour, Extinguishing of burning candles, Lime water test – turning lime water to milky color**

- Test to confirm the completion of fermentation -**Sunken of floating ingredients, Absence of froth, No sound, Appearance of sour taste and alcoholic odour, Burning of candle, No change in the lime water**

- **Sneha kalka (paste) become wick like, No sound when sneha kalka sprinkled over fire, Appearance of foam in taila (oil), Disappearance of foam in ghrita (ghee), Specific color, odour, and taste**¹⁹

- Avalehya siddha laksanas (confections)- **Thready consistency, Sink in water, Solid/rough – to touch, Give finger prints, Attain odor, color, taste of the ingredients**²⁰

Evaluation of drugs (Drug standardization) according to GMP:

- According to 1940 the drug and cosmetics act, control on manufacturing of drugs

- Manufacturers should identify the genuine drugs and purity of crude drugs as well as compound formulations

- The quality of the drug is assessed by fixing the standards for a particular drug / combination

- By these standards adulterants and substitute can be detected from genuine drugs

Parameters to evaluate the standards of different prepared formulations²¹:

Asavas and Aristas (self generated alcoholic preparations)

- Organoleptic characters
- Alcohol percentage
- Ph Value
- Reducing and non reducing sugars
- Specific gravity
- TLC
- Ash content
- Refractive index

Avalehas (confections) –

- Organoleptic characters
- Loss on drying
- Total sugars
- Fat content
- Ash content
- Acid insoluble ash content

Ghrtas and tailas (Medicated ghee and oil)

- organoleptic properties
- Loss on drying at 110 C
- Refractive index at 40 C
- Acid value
- Saponification

- TLC
- HPLC

Curnas (Fine powders-Organoleptic properties)

- Loss on drying at 110 C
- Ash content
- Acid insoluble ash
- Water soluble extractives
- Alcohol soluble extractive
- TLC

CONCLUSION:

- Ayurveda – Needs standardization of crude drugs as well as combined formulations.

- Ayurveda pharmaceutical industries should follow the standards of

Ayurvedic Pharmacopoeia and Formulary of India

- In Combined formulations specific standards parameters to be followed
- Effective treatment completely based on the potency of the drug
- To get the efficacy of the drug in the treatment ,we have to follow some rule i.e.

Dosa, dusya,desa,kala,vaya, agni, bala,etc of the patient

- Proper prescription of the Medicine or formulations, dose, adjuvant, time of administration, route of administration, pathya and apathya to be followed for the specific diseases.
- Treatment will be successful by the potent medicine, proper administration and yukti of the physician

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