

STANDARDISATION IN AYURVEDA - ANCIENT VIS-A-VIS MODERN PERSPECTIVE

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ABSTRACT

Standardization in Ayurvedic formulations deals with ensuring establishment of standards for the quality and purity of raw materials, quality control during the drug manufacturing process, production of a good quality finished product, storage and distribution to maintain the quality of the final product. It is an essential tool for establishing quality control methods for Ayurvedic drugs. **In Ayurveda** standardization has been well defined and documented in the classical as well as the contemporary texts but these have been written with an individualistic intent and not for industrial or commercial purpose. **Materials and Methods:** Meticulous contemplation of the classical literature of Ayurveda was done, the modern guidelines of WHO on standardization of herbal drugs, latest researches on the same via the internet were explored and examined in purview of the latest standardization procedures. **Discussion:** in this article attempt has been made to bring to light the classical references related with standardization, the milestones in this ongoing pursuit have been exhibited, with the use of latest scientific methods being incorporated for a standardized Ayurvedic drug. The need for such measures has increased in the present context due to extensive commercialization of the Ayurvedic pharmacy leading to its inclusion in the Drugs and Cosmetics Act 1940, in the year 1964 and provisions of the various rules thereof in the D&C rules 1945 from the year 1970. **Conclusion:** It can be concluded from the review that standardization in Ayurveda is an ongoing process where one needs to be strictly vigilant about the new scientific methods to study the fine alchemical procedures and the intermediate compounds formed, but at the same time be aware of the classical concepts of the procedure.

Keywords: *Rasaushadhi, bhashajya-pariksha, standardization*

INTRODUCTION

Standard is a parameter which denotes the quality and purity of a material. Standardiza-

tion is the process for the establishment of standard for a particular or drug.

It is the condition in which a standard has been successfully established or it is the imposition of standards or regulations.

It can be better explained with the protocol given in *Charak Samhita* for *Bheshaja Pariksha*¹. It incorporates the principles of standardization starting from cultivation of the raw drug to its usage by the individual patient covering the manufacturing process, storage conditions and method of use.

Materials and Methods

Meticulous contemplation of the classical literature of Ayurveda was done, the modern guidelines of WHO on standardization of her-

bal drugs, latest researches on the same via the internet were explored and examined in purview of the latest standardization procedures, specifically focusing on the various processing techniques employed for the preparation of herbal as well as herbo-mineral drugs. The whole study was a literary one in which the explored literature was analyzed and interpreted.

Review and Discussion

The drugs or substances which are used for various treatment modalities like *vaman* etc. should be analyzed on the parameters as in Table 1.

Table 1: Ancient protocol for Drug Standardization

*Yad dravyabhutam tad vamaadishu yogamuppaiti tasyaapi ayam Pariksha*¹-

<i>Idameva prakritim-</i>	nature of the drug
<i>Evam gunam-</i>	specific properties
<i>Evam prabhavam-</i>	specific effect of the drug
<i>Asmin deshe jaatam-</i>	found or cultivated in particular place
<i>Asmin ritavev samgreeheetam-</i>	collected in the specific season
<i>Evam nihitam-</i>	stored under certain conditions
<i>Evam upaskritam-</i>	processed or prepared in a particular manner
<i>Anaya ch matrya yuktam-</i>	to be used in a specific dose
<i>Asmin vyadhaav-</i>	used in the specific disease-therapeutic indication
<i>Evam vidhasya-</i>	to be used in the prescribed manner- mode of use
<i>Purushasya evam-</i>	to be used in specific type of patient
<i>Tavantam dosham apkarshayati upshamyati va-</i>	duration of use of the drug- either till the vitiated doshas are removed from the body or they are settled to normalcy
<i>Evam Vihitam</i> ² -	the condition of the drug on use
<i>Nishidhamevam</i> ² -	not to be used in certain conditions- therapeutic contraindication
<i>Evam samyuktam</i> ² -	used along with certain drugs- adjuvant use

Ayurveda expounds the guidelines for a good quality effective and safe drug, and these start from the cultivation or original source of the raw material, extend through the drug storage,

manufacturing process to the maintenance of a good quality drug reaching the end consumer and being taken in accordance with a specified method.

The ancient concepts can be understood in light of the current research studies and scientific methodologies as below:

Properties of the medicinal substance-

Prakriti, Guna, and Prabhava is the basic parameters for the selection of the drug which decide the properties and usage of the final product/outcome of the manufacturing process.

The place of cultivation and collection of the raw material³-

The quality of the soil and the nature of the place of cultivation, the state of the drug when it was collected or procured and richness of its nutritional or the medicinal principles (described as *guna* and *virya*) are vital in determining the properties of a plant /mineral product. There is a clear identification of the areas or soils not fit for medicinal or consumption purposes (from cremation grounds, religious places, nearby big trees or near the roads and passages)⁴. Evident relationship between the active content and the place of cultivation has been established through researches done by the Deptt of AYUSH in various institutes. The alkaloid percentages and therapeutic effect vary in specific parts of the same plant; use of *shirish* (*Albizia lebeck*) bark is advisable for the preparation of powder and *ghrita* (medicated ghee) while for the preparation of *Sandhana Kalpana* or *asava arishta* the same plant's *Saar bhaag* (heartwood) is taken⁵. *Shirisharishta* prepared by heartwood of *Shirish* shows better results on pharmaceutical, analytical, pharmacological and clinical parameters when compared with *Shirisharishta* made from the bark of the tree⁶.

The time of collection

The active alkaloid percentage of the product and the efficacy depend on the season of collection of a particular herbal plant or a part of it. The total alkaloid content was maximum (0.50%) in the leaves of *Rawolfia serpentina* in July- August (rainy season) and minimum (0.10%).in May June (hot season). The quantity of reserpine was also maximum in rainy season (>0.10%)⁷.

The alkaloid content percentage in the leaves of *Vasa* at different times of the year shows maximum percentage in the months of August, September & October. The total solid content in *Vasa swaras* also reported similar values⁸.

Storage conditions

Definitive guidelines are given for the collection and storage of certain drugs in the ancient texts e.g. *Madanfala* – the good quality fruit is collected cleaned and placed in a bag of *kusha*, covered in cow dung and placed in husk for 8 days. After this the seeds are dried in shade, seeds are separated and placed in ghee, curd, honey and *til kalka* and dried again. They are stored in a new earthen pot, covered and the pot is suspended from the roof⁹.

Store should be in a clean and dry place free from moisture, insects and rodents, the drug placed in suitable containers made of clay or cloth, preferably suspended from the roof and the place of storage properly fumigated with *krimihar* drugs at regular intervals¹⁰.

Bhaishajya shala or *rasashala* should be constructed at a place near a natural source of pure water, beyond the possible places of contamination such as mortuary/cremation ground or public places or toilets or religious places.

Only qualified and healthy workers were allowed to work in the premises¹¹.

A detailed list of instruments and various equipments is provided followed by clear guidelines to ensure that the pharmaceutical unit had all these organized in a functional manner to avoid cross contamination with separate chambers for each activity such as washing section, fire section, chopping and grinding section, herbal drug store, mineral drug store, prepared drug store¹².

The GMP Guidelines for ASU drug manufacturing in the Drugs and Cosmetic Act and Rules are in place now for the pharmacies to implement¹³

The processing techniques

The raw drug is never used in the state it is in nature, it undergoes through various processing methods designed for a definitive action on the drug as well as on the human body. The principles of synergism and antagonism within various drugs were well understood and put to use while formulating a

compound drug. The potentiation of the effect of a *samshodhana aushadhi* was done by trituration in the water extract of similar acting substance, making it more effective and thereby reducing the therapeutic dose¹⁴.

The potency of a drug can be increased or decreased by addition of drugs or by differential removal of certain substances, effect of time or certain other processing methods¹⁵.

These factors have been researched further and effect of various *shodhan* procedures (detoxification cum purification procedures) of drugs evaluated with special reference to the differential decline in the toxic alkaloid contents with specific mediums. A sharp decline was noted in the values of *strychnine* and *brucine* in *Kuchla* or *nuxvomica* seeds in the traditional method of *shodhan* in *Gomutra*/ Cow's urine and subsequent *bharjan*/ frying in *Goghrita* with separation of seed coat and the embryo¹⁶.

The table below illustrates the differential decrease¹⁷:

Table 2: Effect of detoxification on alkaloids in *Strychnos nuxvomica*

Nuxvomica seeds	Strychnine	Brucine
Crude form	1.92%	0.93%
After <i>shodhan</i> in <i>gomutra</i> and <i>goghrita</i>	0.068%	0.012%

Specific dose of the drug

This aspect signifies the role of posology in treatment. Dose was understood as a major factor for the mild, moderate or fast action of drugs especially *shodhan dravya* used for *vaman* and *virechana*¹⁸.

The dependence of dose on certain patient factors was also evaluated in the form of ten factors to be examined for providing treatment

and the dose and type of medicine as per the type of patient was decided by the physician¹⁹. If the medicine of high potency is used in a disease of less severity then the drug might treat the current disease but it is likely to produce another disease. A drug given in a dose higher than the digestive power or the power of the patient is likely to create a gastric dis-

turbance, syncopal attack etc., a lower dose may result in the failure of treatment²⁰

The dose in itself has no significance; it is the factors such as time, age, digestive power, physical strength, prakriti, status of doshas and the place which are decisive in planning the medicine dose²¹.

Matra also signifies the quantity of any individual drug added to a compound formulation and it forms an important aspect for the standardization of the method of preparation SMP of a compound formulation²²

Certain herbomineral preparations known for their potential dose related toxic effects are with certain additives for accurate dose fixation to ensure safety of the patient. A non sulfur mercurial preparation *Ras Karpura*; therapeutic dose is 1/64-1/32 *ratti* i.e. 1.95 mg to 3.9mg; the dose fixation is done by mixing 625mg *Ras Karpura* with 625 mg *Navsadar Churna*, well ground and mixed with 60 to 720 ml of cold water. The dose of the liquid – 30 -60 drops: the quantity of *Ras Karpura* per dose is 1.736 mg.²³

The crystalline products may be grinded before packing in the individual dispensing size in a dosage form ready for use for the consumer. Grinding and weighing of individual dose of potentially poisonous products is not permissible in patient consumer pack. This arrangement may reduce the adverse drug reaction which takes place due to dose variation²⁴.

Therapeutic indication of the drug

The particular standardized drug is used in specified disease conditions. Clinical research was definitely used by the ancient researchers

to ascertain the use of a certain drug in specific manner in a particular disease condition. Formulations were disease specific or they were made so by the use of a suitable vehicle e.g. *sanjivani vati* should be used in specific diseases with specified dose and appropriate *anupana*²⁵.

Method of administration

The use of adjuvant drugs in the form of *sahapana* or *anupana* to potentiate the therapeutic effects, the liquid mediums serving as carriers or vehicles for delivering the main drug to the target organ. Certain plants are described as “home into a tissue” for example *ashoka* tends to concentrate in uterus; *Punarnava* has an affinity for the kidneys, use of honey and ghee as a vehicle for *saptamrita lauha* for their affinity for the eyes. Addition of rock salt to *trikatu* to target *trikatu* to the site of action; where it is required to function. In obstructive jaundice penetration of *trikatu* in the liver cells is increased by adding rock salt, so that its cholerectic action is enhanced, the penetrating ability of rock salt making it possible²⁶.

A single formulation is used in a variety of disease conditions with a change in the vehicle/ *anupana* of the drug -*Kankayan vati* in *Gulam roga* used with a different vehicle in different types of the disease²⁷.

Nature of patient

The nature of the patient needs to be ascertained for prescribing any individual drug²⁸. It is the factor which decides the nature and quantity of the drug to be used, also if there are certain allergic /*Asaatmya* conditions in the individual. In the current times also the

height and weight of an individual and the allergic conditions are assessed before starting any kind of medication.

Duration of medication

The duration of use of any medication is determined by checking the status of the vitiated humors of the body. The medicine is used till the time the vitiated *doshas* are removed from the body or they are brought to their normal state by shaman chikitsa²⁹. While this factor plays an important role in determining the treatment duration in case of herbal drugs it is of a high significance in case of herbomineral preparations. Mercurial preparations without processing with sulfur are to be used cautiously and only for the duration when the disease symptoms are present; once the patient is cured these should be immediately stopped as their long term use can cause mercury related complications/ toxic effects³⁰.

The present situation

The above said factors clearly give a very wide perspective to the complex subject of standardization of ayurvedic formulations, but

commercialization of the ayurvedic pharmacy has resulted in a need for sustainable objective criteria to define the standards of the drugs on modern scientific grounds. In the scientific world the various methods are being used to standardize herbal and herbomineral drugs. TLC, HPTLC, fingerprint profiles are used for deciding the identity purity and strength of the poly herbal formulations³¹. DNA fingerprinting technique is another important tool for identification of phytochemically indistinguishable genuine drug from its substitute or adulterant³². The new age Petrological studies play an important role in defining the role of metals such as mercury/ copper/ sulfur in therapeutics³³.

To streamline the booming ayurvedic pharmaceutical units, proceedings were initiated to bring the ayurvedic drugs under the purview of The Drugs & Cosmetics act 1940, thereby regulating the manufacture and sale of Ayurvedic Sidha and Unani drugs to ensure a standardized, safe and effective drug. The various milestones in this ongoing process can be summarized in the form of table³⁴:

Table 3: Milestones in ASU Drug Standardization

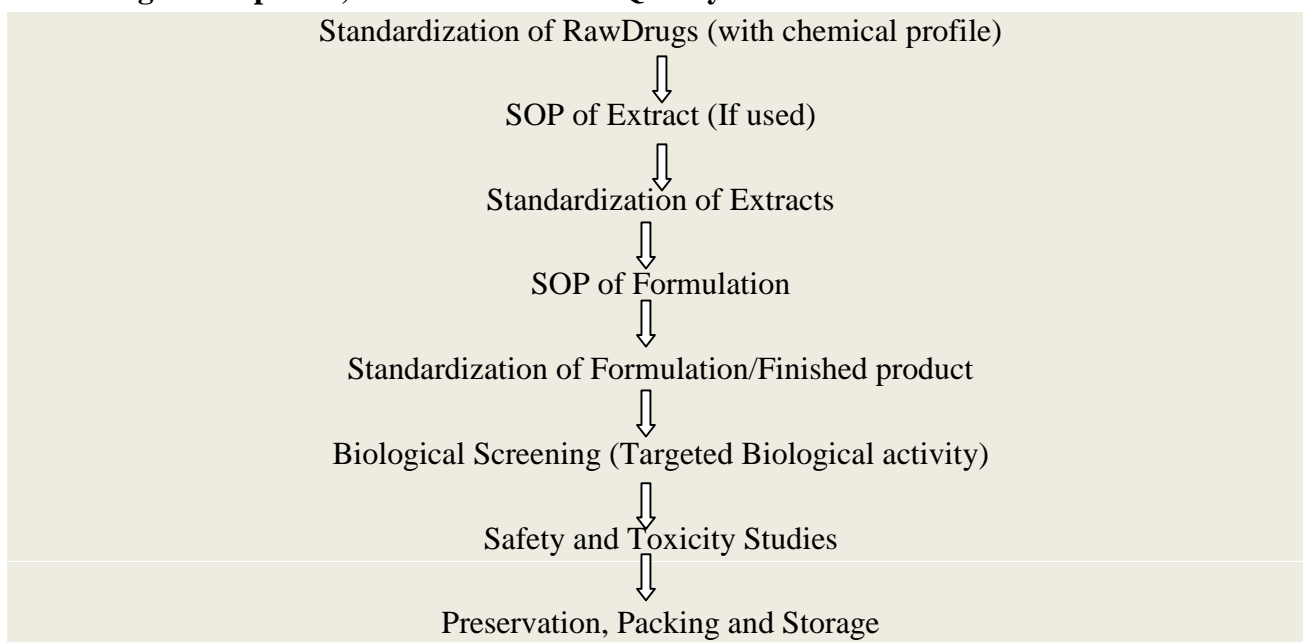
Year	Milestones
1962	Proceedings began with the formation of APC
1/2/1964	ASU drugs came under Act in 1964 under section 33 Chapter 4 A
1969	Ayurvedic Formulary of India Volume I
1970	Work of standardization entrusted to CCRIMH Central Council for Research in Indian Medicine and Homeopathy
1978	API published monographs single herbal drugs
02/11/1992	Rule 161 labeling packing and limit of alcohol in ASU drugs
26/06/1995	Rule 168 Part 19 standards of ASU drugs as in API
July 2001, 2005 23/10/2008	Rule 169 Permitted excipients, additives, flavoring agents, artificial sweetening agents and their acceptable daily intake dose in ASU drugs
07/03/2003	Schedule T; GMP certification mandatory

2003	project started for Development of Standardization of the Method of Preparation (SMP), Pharmacopeial standards and shelf life studies of classical ASU drugs
November 2005	Rule 161B Shelf life notification for ASU drugs: amended again on 1/4/2010 and again on 12/08/2016 with the latest notification on shelf life
01/06/2006	Rule 163A Pharmacopeial lab set up for ASU drugs
2007	API Part 2 Vol 1 published with SMP & Standards for compound formulation
24/12/2008	Rule 170 guidelines for clinical evaluation of ASU drugs and traditional medicines
9/03/2009	Schedule T supplementary guidelines for GMP and QC Rasaushadhi
August 2010	Schedule E1 - changes in the list of poisonous substances
28/03/2013	GCP Guidelines for ASU drugs issued by Department of AYUSH ³⁵

The CCRAS entrusted with this humongous task of standardization has come up with some protocols for drug standardization. These are

presented in the form of flowcharts and tables below:

ASU Drug Development, Standardization & Quality Parameters³⁶



Standardization of a single plant material:

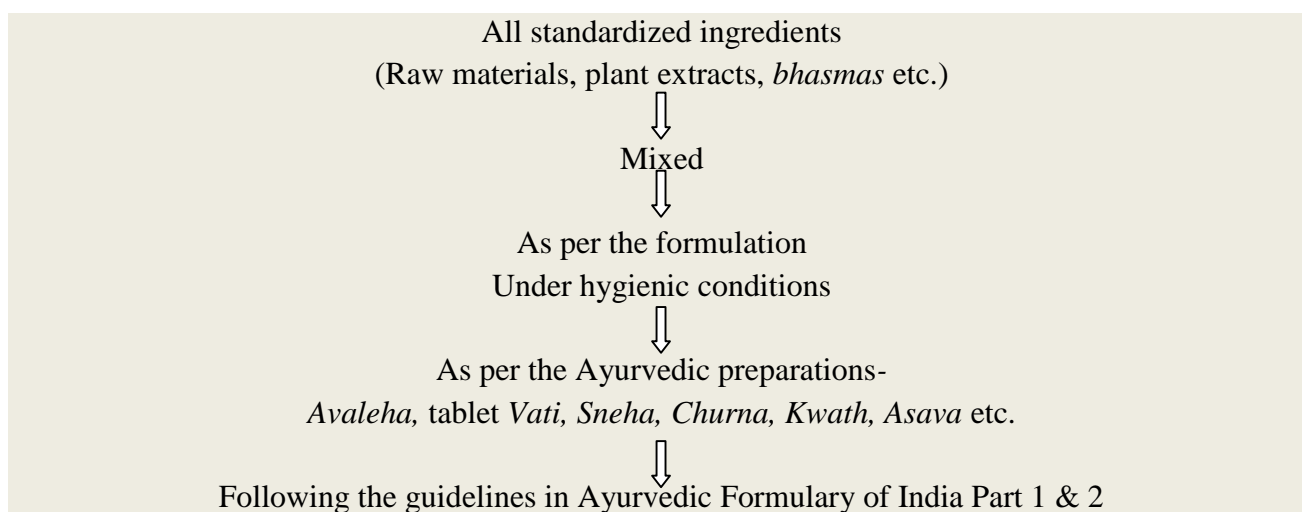
Table 4: Standardization of Single Plant Material³⁷

1	Botanical description Part Used- Botanical Origin-Distribution Adulteration/substitution Season of Collection Site of collection and Stage of plant Substitution of exhausted products/Foreign matter	
2	Description	

	Color- Odor-Taste-Fracture-texture	
3	Identification Macroscopy -Microscopy- Colour test- Chemical test-TLC/HPTLC etc	
4	Physico-chemical Parameters Loss on drying at 105 ⁰ Celsius Total-ash Acid insoluble ash Total solids pH Volatile oil Alcohol soluble extractive Water soluble extractive	
5	Assay for Constituents Marker % (Major compounds) Alkaloids/ flavonoids/ saponin compounds BiologicalActivityEvaluation Bitterness values Astringency swelling factor foam index hemolytic index, etc.	
6	Particle size distribution Bulk density Tap density	
7	Test for heavy/toxic metals Lead Mercury Cadmium Arsenic	WHO/ FDA permissible limits 10.0 ppm 0.30 pm 0.30 ppm 10.0 ppm
8	Microbial contamination Total viable aerobic count Total <i>Enterobacteriaceae</i> Total fungal count	
9	Test for specific pathogen <i>E. coli</i> <i>Salmonella sp</i> <i>S. aureus</i> <i>Pseudomonas aeruginosa</i>	
10	Pesticide residue –Organochlorinepesticides DDT (all derivatives) HCH (all their Isomers) Endosulfan Alderin (used as standard) Organophosphorus pesticides Malathion	Permissible limit 1.0mg/kg 0.3mg/kg 3.0mg/kg 0.05mg/kg 1.0mg/kg

	Parathion	0.5mg/kg
	Pyrethroids	3.0mg/kg
11	Test for aflatoxin	Permissible limit
	B1	0.5ppm
	B2	0.1ppm
	G1	0.5ppm
	G2	0.1ppm
12	Safety Profile	
13	Shelf life	
14	Other Requirements	
15	Packing and labeling	
16	ASU Formulation in which used	
17	Therapeutic Applications	
18	Dose and manner of Administration	

SOP (Standardized Operative Procedures) for finished product³⁸



Standardization of the formulation

Table 5: Standardization of Formulations³⁹

1	Description Color Odor Taste	
2	Identification Microscopy (wherever possible) Colour test Chemical test TLC/HPTLC	
3	Physico-chemical Parameter	

	Loss on drying at 105 ⁰ Celsius Total-ash Acid insoluble ash Total solids pH Volatile oil Alcohol soluble extractive Water soluble extractive	
4	Particle size distribution Bulk density Tap density	
5	TLC/HPTLC – Profile with marker (wherever available)	
6	Assay for Constituents Marker % (Major compounds) Alkaloids/ flavonoids/ saponin compounds	
7	Test for heavy/toxic metals (Permissible limit) Lead Mercury Cadmium Arsenic	As per WHO/ FDA 10.0 ppm 0.30 pm 0.30 ppm 10.0 ppm
8	Microbial contamination Total viable aerobic count Total <i>Enterobacteriaceae</i> Total fungal count	
9	Test for specific pathogen <i>E. coli</i> <i>Salmonella sp</i> <i>S. aureus</i> <i>Pseudomonas aeruginosa</i>	
10	Pesticide residue –Organochlorinepesticides DDT (all derivatives) HCH (all their Isomers) Endosulfan Alderin (used as standard) Organophosphorus pesticides Malathion Parathion Pyrethroids	Permissible limit 1.0mg/kg 0.3mg/kg 3.0mg/kg 0.05mg/kg 1.0mg/kg 0.5mg/kg 3.0mg/kg
11	Test for aflatoxin B1 B2 G1 G2	Permissible limit 0.5ppm 0.1ppm 0.5ppm 0.1ppm
12	Other Requirements (Tablets/Capsules) Uniformity of weight Disintegration time	

	Friability(if tablet) Hardness (if tablet) Biological marker Preservative Binders Diluents	
13	Lethal dose	
14	Optimum effective dose	
15	Mode of administration	
16	Shelf life	
17	Packing and Labeling	

CONCLUSION

Standardization minimizes batch to batch variation; assure safety, efficacy, quality and acceptability of poly herbal formulations. Safety issues regarding the herbomineral preparations in the ASU system of medicine needs to be validated on the basis of various toxicity as well as clinical studies done under stringent International guidelines. Single herbal drugs and their active therapeutic constituents have been identified and extracted out at different levels. The SOP for extraction of plant drugs in Ayurveda have been outlined by the CCRAS under drug standardization. But for poly herbal formulations the key to standardized product lies in the use of standardized good quality raw material, cultivated and procured by Good Agricultural Practices and manufactured under Standard Manufacturing Procedures in a unit following the GMP guidelines.

It can be concluded from the review that standardization in Ayurveda is an ongoing process where one needs to be strictly vigilant about the new scientific methods to study the fine alchemical procedures and the intermediate compounds formed, but at the same time be

aware of the classical concepts of the procedure as well as the drug.

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Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Guleria Praveen & Chandla Anubha: Standardisation In Ayurveda - Ancient Vis-A-Vis Modern Perspective. International Ayurvedic Medical Journal {online} 2017 {cited July, 2017} Available from: http://www.iamj.in/posts/images/upload/2668_2680.pdf