Research Article

Basics of Saveeryata Avadhi of Ayurveda formulations- a review

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ABSTRACT:

In Ayurvedic Classical texts, “Saveeryata avadhi” term is mentioned in context of shelf life of recent era which denotes the time period during which the Veerya (potency) of any drug remains unaffected. Since many centuries, Ayurvedic medicines have been used by people due to its ability to enhance immunity and prevent diseases. Due to lack of scientific standards for the Ayurvedic medicines, Ayurveda does not gain its glory worldwide. Hence, in the current scenario, its a major challenge in front of researchers from this field. Standardization of Ayurvedic formulations can be achieved by pharmacognostic identification, physical, chemical, biochemical estimation and determination of active phytoconstituents in the plant as well as in formulations. Standardization of any drug needs laborious effort because many factors directly influence the quality and purity of the drugs. stability testing is needed to ensure the quality of herbal products which is an evidence for the quality of the finished product. Hence stability testing is essential to improve the quality of the herbal products

Keywords: Stability, Shelf life, Stabilizer, Ayurveda doses form

INTRODUCTION

In Ayurvedic Classical texts, “Saveeryata avadhi” term is mentioned in context of shelf life of recent era which denotes the time period during which the Veerya (potency) of any drug remains unaffected and above certain threshold beyond which it may lose its potency to some extent but not completely devoid of it provided that it is

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stored in the mentioned condition. The word Veerya has got different meanings as per Sanskrit-English Dictionary namely, heroism, valor, vigor, strength, virility, energy, firmness, courage, potency, efficacy, splendor, luster, and dignity. Hence, Veerya is considered to be the most active principle of a drug among rasa, guna, vipaka, and prabhava responsible for overall effect of the same.

Since many centuries, Ayurvedic medicines have been used by people due to its ability to enhance immunity and prevent diseases. Due to lack of scientific standards for the Ayurvedic medicines, Ayurveda does not gain its glory worldwide. Hence, in the current scenario, its a major challenge in front of researchers from this field. Standardization of Ayurvedic formulations can be achieved by pharmacognostic identification, physical, chemical, biochemical estimation and determination of active phytoconstituents in the plant as well as in formulations. Standardization of any drug needs laborious effort because many factors directly influence the quality and purity of the drugs. Ayurvedic medicine is available in a variety of dosages form such as Avaleha (electuary), Asava-Arishtha (alcoholic preparations), Ghrita (fat based medicine), Taila (oil based medicine), Churna (powder), Swaras (juice), Vati (tablet), Kwath (decotion), and much more.

Currently Ayurvedic Preparations are accepted all over the world. The Major weakness of herbal medicines is consistency in the quality of the product over a range of time. The products efficacy, safety, and ethical issue have to be confirmed before launching in the market. Herbal medicinal products have to fulfill the legal requirements with regard to quality, including stability testing, but have certain particularities such as a complex nature, an often low concentration of constituents and a natural variability of their raw materials. Due to their natural origin, questions on microbiological quality arise more often for herbal medicinal products than for chemically defined medicinal products. Any considerable changes in the quality of the product over a time must be detectable. So stability testing is needed to ensure the quality of herbal products which is an evidence for the quality of the finished product. Hence stability testing is essential to improve the quality of the herbal products.

**MATERIAL AND METHOD**

References regarding stability or shelf life were collected from various classical and Ayurveda published works, published research papers from Pub Med, Google Scholar, ICH guideline and WHO guideline, recent amendment of shelf life of Ayurvedic dosage forms published by department of AYUSH and compilation was done. Concept of shelf life was studied in detail and conclusion was drawn.

**REVIEW OF LITERATURE**

**Ayurveda Aspects**

Ayurveda, the holistic system of medicine, describes many varieties of dosage forms like Vati, Gutika, Asava-arista, Lepa, Avaleha, Bhasma, etc. Various efforts are being continued for maintaining the effective span of a medicine i.e. protecting and prolonging the desired state of a Ayurveda medicine. Various meticulous methods for collection of drugs, their storage and different processes before usage are examples of bhashja samskaras for prolonging shelf life of drugs. Evolution of panchavidha kashaya kalpanas and its upkalpanas are outcomes of these efforts. According to need, various formulations are designed which over the period of time are being tested for their effectiveness and depending on these observations life span of drugs i.e. period for which it can protect its own gunas are calculated which is termed as saveeryata avadhhi of medicine.

Word “Veerya” represent the potential of a drug to give a desired action or karma which is nothing but its guna. The period up to which a specific medicine can possess its gunas/veerya unchanged is termed as Saveeryata avadhhi of medicines. The shelf life of a preparation depends upon the ingredients used, method of preparation and form of the medicament. In Ayurvedic text the shelf life is termed as “Savirayata avadhhi”.

“Saveeryata Avadhi” means the Time Period during which the Veerya (Potency) of any Drug remains unaffected from the environmental factors or microbial contamination. Different types of Kalpanas (Preparations) are included in therapeutic system of Ayurveda, which are further classified into UpaKalpanas. They generally represent different kinds of dosage forms like Swarasa, Kwath, Kalka, Churna, Vati, Taila, Lepa-malahara, Asava and Arista, Avaleha, Bhasma, Pisti etc. Among them some have very short shelf life and some of them have long shelf life i.e. ranging from few hours to many years. After their mentioned shelf

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life they loose their Rasa, Veerya, Varna and Gandha etc. The concept of Saveeryta Avadhi (shelf life) for different Ayurvedic dosage forms are specified by the Acharya after 12th century, it was considered in various authentic Ayurvedic texts like Sharangadhar Samhita, Yogaratnakar and Vangasen etc.\textsuperscript{15,16}

Ayurvedic Formulary of India (AFI) also has stated the time period from the date of manufacture within which the formulations should be consumed for best results.\textsuperscript{17}

**Saveeryta Avadhi of Various Kalpana**

Acharya Sharangadhar has mentioned that all herbal preparations loose their potency and original form after one year. They are as \textsuperscript{18} -

a. Churna - 2 month
b. Gutika & leha - 1 year
c. Medicated ghee & oil - upto 4 month
d. Laghu paka ausadhas - 1 year
e. Asavarista - infinite period (older is the better).

In general medicines which are laghupaka lose potency in one year whereas dhatu kalpas (herbo-mineral preparations) and asava arishtas (self fermented liquids) preserve their potency with advent of time.\textsuperscript{19} The stability or shelf-life of different preparations are explained in the context of the storage techniques and packaging methods of those days of Sharangadhara i.e. 13th century A.D. So, storage condition becomes a most important aspect which affects on shelf-life of the product.

Apart from the description of Saveeryta avadhi in Sharangadhar samhita, following table show description of Vanga Sen and Yogaratnakar.

Saveeryta avadhi of different Ayurvedic dosage forms as per classics\textsuperscript{20} -

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Saveeryta Avadhi</th>
<th>VangaSen</th>
<th>Sharangadhar Samhita</th>
<th>Yogaratnakar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kwatha (Decoction)</td>
<td></td>
<td>-</td>
<td>-</td>
<td>03 Hours</td>
</tr>
<tr>
<td>Kalka (Paste)</td>
<td></td>
<td>-</td>
<td>-</td>
<td>03 Hours</td>
</tr>
<tr>
<td>Swaras (Expressed juice)</td>
<td></td>
<td>-</td>
<td>-</td>
<td>03 Hours</td>
</tr>
<tr>
<td>Anjana (Collyrium)</td>
<td></td>
<td>-</td>
<td>-</td>
<td>03 Months</td>
</tr>
<tr>
<td>Churna (Powder)</td>
<td></td>
<td>-</td>
<td>02 Months</td>
<td>03 Months</td>
</tr>
<tr>
<td>Vati (Pills)</td>
<td></td>
<td>-</td>
<td>12 Months</td>
<td>-</td>
</tr>
<tr>
<td>Guda / Avaleha</td>
<td>12 Months</td>
<td>12 Months</td>
<td></td>
<td>06 Months</td>
</tr>
<tr>
<td>Ghrita &amp; Taila (Oil &amp; Fat based Preparation)</td>
<td>06 Months</td>
<td>04 Moths</td>
<td>12 Months</td>
<td></td>
</tr>
<tr>
<td>Asava &amp; Arishtha (Alcoholic Preparation)</td>
<td>-</td>
<td>Long term Stability</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Dhatu (Metallic Preparation)</td>
<td>-</td>
<td>Long term Stability</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Rasa (Mercurial Preparation)</td>
<td>-</td>
<td>Long term Stability</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

**Drug and Cosmetics (Amendment) Rules , 2009**

- In India, for Ayurveda Drugs The drug and cosmetic act was laid in 1940. From there onwards amendments were done regularly. Recently it was amended in 2009.

- After rule 161A, the following rule has been added namely: ‘161 B’ - The date of expiry of Ayurveda, Siddha and Unani (ASU) medicines shall be displayed on the label of container or package of an Ayurvedic, Siddha and Unani drugs.

- The shelf life of Ayurvedic medicines was updated by the Ministry of Health and Family Welfare, Department of AYUSH.
### Shelf Life Period of Ayurvedic Medicine

<table>
<thead>
<tr>
<th>Name of Dosage Form</th>
<th>Shelf Life according to Classical Texts</th>
<th>Shelf Life according to Drug and Cosmetics (Amendment) Rule,2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Churna / Kwatha Churna</td>
<td>2 Moths</td>
<td>2 Years</td>
</tr>
<tr>
<td>Gutika (Varti/gutti/pills)</td>
<td>1 Year</td>
<td>3 Year</td>
</tr>
<tr>
<td>Gutika / Tablet (contains maharasa, uparasa, sadharanasa varga dravya Bhasma)</td>
<td>1 Year</td>
<td>5 Year</td>
</tr>
<tr>
<td>Vati (Tablet)</td>
<td>1 Year</td>
<td>2 Year</td>
</tr>
<tr>
<td>RasaAushadhis</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Aasava, Arishtha</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Guggulu</td>
<td>1 Year</td>
<td>5 Years</td>
</tr>
<tr>
<td>Mandoor Lauha</td>
<td>Older is better</td>
<td>10 years</td>
</tr>
<tr>
<td>Ghrita</td>
<td>4 -6 Months</td>
<td>2 Years</td>
</tr>
<tr>
<td>Taila</td>
<td>4 -6 Months</td>
<td>3 Years</td>
</tr>
<tr>
<td>Arka</td>
<td>1 Year</td>
<td>1 Year</td>
</tr>
<tr>
<td>Dravaka Lavana</td>
<td>1 Year</td>
<td>5 Years</td>
</tr>
<tr>
<td>Kshara</td>
<td>1 –5 Year</td>
<td>5 Years</td>
</tr>
<tr>
<td>Lepa Churna</td>
<td>2 Months</td>
<td>3 Years</td>
</tr>
<tr>
<td>Lepa and Malahara / Ointments/ Liniments/ Gel/ Creams</td>
<td>2 Months</td>
<td>3 Years</td>
</tr>
<tr>
<td>Pravahi kwatha (with preservatives)</td>
<td></td>
<td>3 Years</td>
</tr>
<tr>
<td>Varti</td>
<td>1 Year</td>
<td>2 Years (one time use)</td>
</tr>
<tr>
<td>Ghana Vati</td>
<td>1 Year</td>
<td>3 Years</td>
</tr>
<tr>
<td>Kupipakva rasayana</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Parpati</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Pishthi and Bhasma</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Bhasma of Swarna, Rajat, Louha, Mandoora, Abhara-ka, Godanti, , Shankha etc.</td>
<td>Older is better</td>
<td>No expiry date</td>
</tr>
<tr>
<td>Bhasma of Naga, Vanga,Tamra</td>
<td>Older is better</td>
<td>5 Years</td>
</tr>
<tr>
<td>Syrup/ Oral liquid</td>
<td>4 Months upto 1 Year</td>
<td>3 Years</td>
</tr>
<tr>
<td>Paka/ Granule/ Khanda</td>
<td>2 to 4 Months</td>
<td>3 Years</td>
</tr>
<tr>
<td>Dhoopana / Inhalers</td>
<td>6 Months</td>
<td>2 Years</td>
</tr>
</tbody>
</table>

Naga bhasma, Vanga bhasma and Tamra bhasma starts solidifying after 5 years. So, there is needed the repetition of the last process of Bhasma (with one or two puta). Those dosage forms having ‘No expiry date’ become better with the passage of time. For such products, it should be mandatory of documentation and keeping records for 10 years.\(^{21}\)

Stability testing is termed as a complex process because of involvement of a variety of factors influencing the stability of a pharmaceutical product. These factors include stability of the active ingredient(s); interaction between active ingredients and excipients, manufacturing process followed, type of dosage form, container/closure system used for packaging and light, heat and moisture conditions encountered during shipment, storage and handling.\(^{22}\)
A pharmaceutical product may undergo change in appearance, consistency, content uniformity, clarity (solution), moisture contents, particle size and shape, pH, package integrity thereby affecting its stability. Such physical changes may be because of impact, vibration, abrasion, and temperature fluctuations such as freezing, thawing or shearing etc.\textsuperscript{23}

The chemical reactions like solvolysis, oxidation, reduction, racemization etc. that occurs in the pharmaceutical products may lead to the formation of degradation product, loss of potency of active pharmaceutical ingredient (API), loss of excipient activity like antimicrobial preservative action and antioxidants etc. Stability of a pharmaceutical product can also be affected because of microbiological changes like growth of microorganisms in non sterile products and changes in preservative efficacy.\textsuperscript{24}

**Definition:**

Stability is the capability of a specific formulation in a particular container/closure system to remain within its physical, chemical, microbiological, toxicological, therapeutic specifications, and is always expressed in terms of shelf life.\textsuperscript{25}

Shelf life is “The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.”\textsuperscript{26}

The USP defines the stability of pharmaceutical product as “extent to which a product retains within specified limits” and throughout its period of storage and use (i.e. its shelf life) the same properties and characteristics that it possessed at the time of its manufacture.\textsuperscript{27}

Stability is the only way that assures whether the drug is within acceptance criteria or not. Stability comes into focus when the quality and efficiency of the drug are concerned. Literal meaning of stability is the capacity of a drug product to remain within specifications established to ensure its identity, strength, quality and purity. Instability of the drug can cause undesired change in performance that causes product failures.\textsuperscript{28}

So, it can be understood that

- Stability is the time lapse during which the drug product retains the same properties and characteristics that is possessed at the time of manufacture.

- Stability of a product is expressed as the expiry period or technically as shelf life.

- Stability of finished pharmaceutical products depends, on the one hand, on environmental factors such as ambient temperature, humidity and light, and, on the other, on product-related factors, e.g. the chemical and physical properties of the active substance and of pharmaceutical excipients, the dosage form and its composition, the manufacturing process, the nature of the container-closure system and the properties of the packaging materials. For established drug substances in conventional dosage forms, literature data on the decomposition process and degradability of the active substance are generally available together with adequate analytical methods.

**Chronological Background**

Jordan was the one to give the name for Stability testing in the pharmaceutical companies. The need arose when regional office organized a workshop for validation of expiry dates of drug in Amman. The workshop ordered every medical authority to collaborate with every pharmaceutical company to guide them about the importance of drug stability and expiry date.\textsuperscript{29}

Thus International Conference on Harmonization thus took a step to implement these guidelines. FDA issued its first stability guidance in 1987. Considerable efforts were taken, to harmonize the stability practices within the ICH region then after in the early 1990. As a result to the efforts, International Conference on Harmonization (ICH) was established in 1991 and various guidelines for drug substance and drug product came into existence regarding their quality, safety and efficacy. These guidelines are called as quality, safety, efficacy and multi disciplinary (also called as Q, S, E and M) guidelines.\textsuperscript{30}

Work on stability of pharmaceutical products was initiated by the WHO in 1988 and the WHO Guidelines on Stability Testing for Well Established Drug Substances in Conventional Dosage Forms were adopted in 1996 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations following extensive consultation. In 2000, discussions began between the International Conference on Harmonization (ICH) expert working group Q1 (stability) and the WHO to harmonize the number of stability tests and conditions employed worldwide.\textsuperscript{31}
Need of Stability Study:
- Product instability of active drug may lead to under medication due to lowering concentration of the drug in dosage form.
- During decomposition of active drug toxic products may be formed.
- Instability may be due to changing in physical appearance though the principles of kinetics are used in predicting the stability of drug there different between kinetics and stability study. The goal of chemical kinetics is to elucidate reaction mechanism.
- In stability studies, the objective is to establish an establish an expiry date.
- The most important challenge faced by Ayurvedic formulations arises from lack of complete evaluation of its constituents, due to its complex nature. Evaluation of constituents is necessary to ensure quality, purity and stability of the finished product. Stability study provides evidence on how quality of a drug substance or product varies with time under influence of variety of environmental factors such as, temperature, humidity and light and also to establish a retest period for the drug substance or product and recommended storage conditions. So we can say stability study is necessary as an assessment of product quality.
- The nature of drug, their mode of administration, doses & the time duration specially its expiry date & expected effect, ultimately decides the success of medicinal drugs & treatment of that pathy. Hence it is very important to study the shelf life of dosage form according to pharmaceutical parameters. According to Ayurvedic pharmaceutical science, preparations remain potent up to limited timespan (13th century A.D., sharanagdha samhita ), after which they start degrading gradually thus losing their efficacy. The most important challenge faced by Ayurvedic formulations arises from lack of complete evaluation of its constituents, due to its complex nature.

Types of Stability Study:
Five stabilities of drug must be considered
a. Physical stability
b. Chemical stability
c. Microbiological stability
d. Therapeutic stability
e. Toxicologic stability

1. Physical: The original physical properties, including appearance, palatability, uniformity, dissolution and suspend ability are retained.

2. Chemical: Each active ingredient retains its chemical integrity and labeled potency within the specified limits.

3. Microbiologic: Sterility or resistance to microbial growth is retained according to the specified requirements. Antimicrobial agents retain effectiveness within specified limits.

4. Therapeutic: The therapeutic effect remains unchanged.

5. Toxicological: No significant increase intoxicity occurs.

Chemical stability is important for selecting storage conditions (temperature, light, humidity), selecting the proper container for dispensing (glass vs. plastic, clear vs. amber or opaque, cap liners), and anticipating interactions when mixing drugs and dosage forms. Stability and expiration dating are based on reaction kinetics, that is, the study of the rate of chemical change and the way this rate is influenced by concentration of reactants, products, and other chemical species and by factors such as solvent, pressure, and temperature. In considering chemical stability of a pharmaceutical, one must know the reaction order and reaction rate.

The reaction order may be the overall order, or the order with respect to each reactant.

Ayurveda has given importance to chemical composition of a drug because quotation indicating that asava arishta, metallic preparations are more stable and can preserve their gunas for a longer duration is clear-cut observation based on their chemical stability.

Stability Study according to Objective:


b. Short Term Stability Study – for development of the product.

c. Accelerated Stability Study – for the development of the product.

d. Real Time Stability Study – for registration dossier.
The main objectives and uses of stability testing are show in table

<table>
<thead>
<tr>
<th>Objective</th>
<th>Type of study</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>To select adequate formulation &amp; container -Closure system</td>
<td>Accelerated</td>
<td>Development of the Product</td>
</tr>
<tr>
<td>To determine shelf life &amp; storage condition</td>
<td>Accelerated &amp; Real time</td>
<td>Development of the Product &amp; of the registration dossier</td>
</tr>
<tr>
<td>To substantiate the claimed shelf life</td>
<td>Real time</td>
<td>Registration dossier</td>
</tr>
<tr>
<td>To verify that no changes have been introduced in the formulation or manufacturing process that can adversely affect the stability of the product</td>
<td>Accelerated &amp; Real time</td>
<td>Quality assurance in general, including quality control</td>
</tr>
</tbody>
</table>

Pharmaceutical products are generally studied for stability profile at accelerated temperature and humidity, the experimental findings of which can be very helpful to predict reliable self-life or expiry date at room temperature by adopting certain assumptions and criterions.

Real time study is a long procedure. The manufacturer finds it difficult to wait till the drug degrades naturally at room temperature.

**FACTORS AFFECTING DRUG STABILITY**

a. Temperature  

b. Moisture  

c. Light  

d. Concentration  

1. **Temperature**- High temperature accelerates oxidation, reduction and hydrolysis reaction which lead to drug degradation.

2. **PH**- Acidic and alkaline pH influences the rate of decomposition of most drugs. Many drugs are stable between pH 4 and 8. Weekly acidic and basic drugs show good solubility when they are ionized and they also decompose faster when they are ionized. So if the pH of a drug solution has to be adjusted to improve solubility and the resultant pH leads to instability then a way out of this tricky problem is to introduce a water miscible Solvent into the product.

3. **Moisture**-
   - Water catalyses chemical reactions as oxidation, hydrolysis and reduction reaction.  
   - Water promotes microbial growth.

4. **Light**- Affects drug stability through its energy or thermal effect which lead to oxidation.

5. **Concentration**- Rate of drug degradation is constant for the solutions of the same drug with different concentration. So, ratio of degraded part to total amount of drug in diluted solution is bigger than of concentrated solution.
Basically, there are three forms of Stability tests:

1. **Physical & Chemical Integrity Test**: which is for Evaluation of Colour, Odour, pH Value, Viscosity, Texture, Flow and Emulsion Stability.

2. **Microbiological Test**: which is for evaluation of the degree of contamination with Bacteria, Fungus, Mold & Yeast etc.

3. **Packaging Stability Test**: Which is for evaluation of the impact of packaging on the product.

**Purpose of stability tests**

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and to establish a retest period for the drug substance or a shelf-life for the drug product and recommended storage conditions.  

**Preservation of drugs**: This process is in three stages - use of stabilizers, packaging and proper storage.

**Concept of Stabilizer**: Stabilizers are the substances which are used to control the stability of formulations or pharmaceutical finished products. The shelf life period of pharmaceutical product can be increased by utilizing proper stabilizers, and then the medicine has to be packed. In ancient period there was no any usage of stabilizers mentioned. In that time they prepared and processed medicines in different way, which may leads to the potency period or shelf life period of the medicines. At present the most important stabilizers are the antioxidants and preservatives. Antioxidants are the substances which are added to a pharmaceutical formulation to prevent the oxidation or the oxidative degradation of the drug. An ideal antioxidant should be stable and effective against a wide range of pH. It should be colourless, non-toxic, non irritant, thermo-stable and compatible with the ingredients and packaging material. Some common antioxidants are ascorbic acid, sodium-bi-sulphate, sodium thiosulphate, propylgallate, butylated hydroxytoluene (BHT), butylated hydroxyl anisole (BHA), tocopherols, etc.

Preservatives are used in the formulation to prevent the growth of micro-organism. They are added to all formulations which are to be stored for prolong periods of time and the ingredients of which support microbial growth. Mainly carbohydrate and water containing ingredient provides very good medium for growth of bacteria and moulds. So, they must be suitably preserved. The property of preservatives should be non toxic, effective against wide range of micro-organisms, compatible with the ingredients of the formulation. They should be free from odour, remains stable and preserve the preparation and should have well solubility power when it used in liquid or semi-solid preparations. There are many preservatives are used such as Benzoic acid & Sodium benzoate (0.1% To 0.2%), methyl paraben & propyl paraben (0.1% to 0.2%), sorbic acid & its salts (0.05% to 0.2%), phenol (0.2% to 0.5%), Chlorbutanol (0.5%), phenyl mercuric nitrate (0.002% to 0.005%), salicylic acid (0.1%), cetrimide (0.2% to 0.5%), chlorocresol (0.05% to 0.1%), bronopol, ethyl paraben, butyl paraben, etc. The pharmaceutical preparation which contains medicament(s) having bactericidal properties, there is no necessary to add preservatives. In most cases no single preservative posses all the qualities of its choice. Therefore it becomes necessary to use a combination of preservatives to prevent the growth of micro-organisms.

**Concept of Packaging**: According to the Charak Samhita, a drug or medicine should be packed in such type of vessel(s) which must have the Anurup guna i.e. the packaging material should not interfere with the physical, chemical or biological property of the drug.

The Churna, Taila, etc should be preserve in a new kalash (earthen vessel with broader body and narrow mouth) and they should be stored in dark place. Most of Ayurvedic formulation packed in earthen vessels and tied with cloth, and some time muddy-smeread cloth was used as sealing material.

According to the modern concept, the package must have the quality of giving primary protection against mechanical hazards such as temperature, light, moisture, any contamination and exposure to air. The pharmaceutical products are suitably packed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. Packaging is the art of science which involves preparing the articles for storage, transport, display and use. If a prepared formulation is not packed properly, the whole material may be lost after certain time. A package may consist of following things such as container, closure, cartoon and box. Container is a device in which the drug or pharmaceutical products are enclosed and is in direct contact with the drug. Closure is a device which seals the container to pass of oxygen, CO2, other gases, moisture, micro-organisms and pre
vents the loss of volatile matters. It has also a great role of preventing the loss of medicaments during handling and transportation. Carton is the outer covering which gives the secondary protection against mechanical and environmental hazards. A box is a device which is generally used for packing multiples of the products. It gives the primary protection from external hazards during handling and transportation.44,45,46

Now-a-days there are several types of containers are available in the market. On the basis of closure such as well close containers, airtight containers, hermetically sealed containers (sealed by fusion), light resistant containers, single dose containers, multi dose containers, aerosol containers, etc. On the basis of shape some containers like glass or polythene bottles including narrow or wide mouthed, dropper bottles, Collapsible tubes, ampoules, vials, polythene packets for intravenous fluids, polythene bottles for intravenous fluids, aerosol containers, envelopes, strips, cartoons, boxes, drums, etc.47

Storage of Drugs : The medicament should be stored under conditions that prevent Contamination and Degeneration as far as possible. It should be preserved in Airtight Container and not exposed to Direct Sunlight. High Temperature should be avoided.

Storage Temperature 48:
Cold Place : should preserved in temperature not exceeding 80C.
Cool Place : should preserved between 80-150C.
Room Temperature : controlled room temperature between 150-300C
Warm Place : preserved between 300-400C.
Excessive heat : preserved above 400C.

Discussion : Stability is aimed at assuring that the product remains within specifications established to ensure its identity, strength, quality and purity. It can be interpreted as length of time under specific conditions and storage that a product will remain within the predefined limits for all its important characteristics. The main purpose of conducting stability testing of pharmaceutical products is to ensure the efficacy and quality of active compounds in product, to establish shelf life or expiration period and to support the label claim. The stability data on any dosage form includes selected parameters that together form the stability profile. This stability profile is the basis for assigning the storage conditions and shelf life to pharmaceutical products. The design of the stability pro-
gram for the finished product should be based on the knowledge of the behavior and properties of the drug substance and the dosage form.49,50,51

The shelf life of Ayurvedic preparation in olden days were told lesser time. Like Churna preparations were mentioned to have only 2-3 months of stability but their raw materials have more stability. It may be due to the greater surface area which is needed for its efficient absorption. This Churnas are further developed in Vati form using different kinds of binders like guggulu, shilajatu, etc. as a bioactive binding agents. These are required to fix the dose of a drug and to increase the stability again up to one year. In case of Asava and Arista, the amount of shelf generated alcohol is act as self preservative. Adhamalla has clearly mentioned that all of the Churnas may not have the same shelf life and it depends upon the ingredients which it contains. The drug containing the substance which is hygroscopic in nature, then there have chances of lesser shelf life period.52 The major aim of pharmaceutical stability testing is to provide reasonable assurance that the products will remain at an acceptable level of fitness/quality throughout the period during which they are in market place available for supply to the patients and will be fit for their consumption until the patient uses the last unit of the product.53

In case of Ayurveda drugs, they are a mixture of many chemical components which interact with each other and also with environment so it is not possible to decide its stability on the basis of its one constituent. Selecting active principle of a drug for deciding stability of a medicine can be an alternate approach. From the point of Ayurveda selecting a Selective Reactive Mioety as drug and measuring its actual presence in preparation will not serve the purpose of Ayurveda. Active principles may play major role in total action of drug but cannot be solely responsible for it. Ayurveda believes in principle of ‘Treat man whole and take the drug as whole’ so it is not a specific active principle but the whole drug is responsible for its action.54

According to Ayurveda every drug is panchabhautika in nature. Various samskaras which are mentioned in RasaShastra and Bhaishajya Kalpana have their role in extension of shelf life. Stability of drug depends on panchabhautika composition of it. Prithvi and mahabhuta are responsible for maintaining it in yatha sthiti. Increase in agni and vayu mahabhuta composition of dravya enhances speed of degeneration of drug by augmenting processes of digestion and de-
composition. Thus applying this logic to above explained kalpanas and their mahabhuta predominance churna has maximum surface area and prepared from grinding procedures which increase vayu mahabhuta composition in it and lead to easy decomposing and early expiry. Churnas are having ruksha guna in them and can easily absorb moisture which is a measure factor in reducing its stability. Gutika made up of same churna has different mahabhuta predominance i.e. increase in murtata of dravya which indicates prithvi mahabhuta predominance in it. Reduced surface area and increased vicinity between particles reduces chances of moisture and external contamination.

Oil preparations are termed as murchita snehas which mean fats are broken partially and drugs which are processed with fats acquire inter molecular spaces between fat molecules and may form loose bonds with them enhancing their stability. These preparations are nearly free from water content and fats themselves act as preservation media which further increase its stability.

Thus stability of Ayurveda drugs depends on pancha mahabhuta predominance in which agni & vayu are responsible for its early expiration whereas prithvi and jala mahbhuta delay the expiry.

Conclusion

Stability testing is the main component in the pharmaceutical development program for a new drug as well as new formulation. Pharmaceutical stability is a critical quality attribute. Stability tests are carried out so that recommended storage conditions and shelf life can be included on the label to ensure that the medicine is safe and effective throughout its shelf life. Any deviation from the established stability profile could affect the quality, safety and efficacy. Therefore, Plan well and use science based approach; consult the experts/regulators, as needed Stability studies should be planned on the basis of pharmaceutical R&D and current regulatory requirements as per the climatic zone.

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