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Review Article

SHELF LIFE PERIOD OF AYURVEDIC MEDICINE IN CONTEXT TO ANCIENT AND MODERN LITERATURE

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ABSTRACT

Ayurveda is the oldest system of treatment. There are many varieties of dosage form like Vati, Gutika, Asava- arista, Lepa, Avaleha, Bhasma, etc. which has specific shelf life period mentioned by ancient Acharyas. But in the year 2005, the Ministry of health and family welfare published the Drugs and Cosmetics (Amendment) Rules, 2005, rule 161-B date of expiry of Ayurveda, Siddha and Unani (ASU) medicines where is mention the prolong shelf life period of ASU medicine. This prolong shelf life is due to the modern packaging technology and usage of stabilizers such as anti-oxidants and preservatives. These are prevents the oxidation of formulation and help to retard the growth of micro-organism. The packages give the protection against the environmental hazards. Now-a-days stability study is performed under different condition of temperature and humidity. After that the shelf life period is expressed in the form of expiry date and mentioned on the labels of medicine or food, etc.

***Key word**: Dosage form, Shelf life, Packaging, Stabilizer.*

INTRODUCTION

In Ayurvedic text the shelf life termed as "Saviryata avadhi". It means the time period during which the potency(Virya) of a drug remain unaffected due to environmental factors or from microbial contamination.[1] Different types of Kalpanas (preparations), are included in therapeutic system of Ayurveda, which further classifies into upakalpanas(sub-preparations). They are generally represent different kinds of dosage forms like Swarasa(juice), Kwath(decoction), Kalka(paste), Churna(powder), Vati(tablet), Taila(oils), Lepa-malahara(ointment), Asava and Arista(self generated alcohol), Avaleha(electuary), Bhasma(nano particle), Pisti(fine particles), etc. Among them some have very short shelf life period even few hours, and some of them have prolong shelf life period even no expiry date. The shelf life period was mentioned by the scholars after 12th century AD.[1, 2] Modern concept of shelf life is the time period during which the active pharmaceutical ingredient(s) or finished pharmaceutical product is expected to remain within the approval stability specification, provided that it is stored under the conditions defined on the label of container.

The shelf life of any drug or medicine is expresses as 'Expiry date'. The expiration date of any drug or medicine provide the time period up to which the drug possess full safety and potency. But there is deference between shelf life and expiry date. A dosage can be safe after passing the shelf life, but the quality is not present in it. In case of expiry date, after expiry date generally there is no guarantee of safety.

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MATERIALS

The stability study is perform to know the quality of a drug or its product varies with the time under the conditions of environmental factors such as temperature, humidity, light and to find out the Shelf life period of the product and storage condition. Recently, there are two guidelines namely ICH guideline and WHO guideline. These are provided the proper guideline and details parameter on which stability study can be done. There are several studies over Shelf life has been done on Ayurvedic formulations. There after department of AYUSH publish the recent amendment of shelf life of Ayurvedic dosage forms, different from the ancient authors' view. This study is a review to compare the changes between two concepts.

Shelf life according to ancient Ayurvedic scholars and Modern view: There does not found any clear idea about the shelf life of Ayurvedic formulations before 11th century AD. The major text of Ayurveda like Charak Samhita and Susruta Samhita, there was no clear statement about the shelf life of Ayurvedic Dosage forms. In 13th century AD it was considered in various authenticated texts like Sarangadhar Samhita, Yogaratnakar, etc. The shelf life of Ayurvedic medicines were updated in Drugs and Cosmetics (Amendment) Rule, 2005, by Ministry of Health and Family Welfare, department of AYUSH. This rule has been added in the Drugs and Cosmetic Rules, 1940., named, '161 B'- The date of expiry of Ayurveda, Siddha and Unani (ASU) medicines shall be conspicuously displayed on the label of container or package of an Ayurvedic, Siddha and Unani drugs, after which they shall not be sold or in circulation [3,4].

The shelf life period of Ayurvedic dosage forms according to ancient scholars and updated shelf life of same Ayurvedic dosage forms is represented in table 1.

Table 1: Shelf life period of Ayurvedic medicines (Ancient scholar's and modern view) [3,4,5]

Name of Dosage Form	Shelf Life According to Ancient Authors	Shelf Life According to Drugs & Cosmetics (Amendment)Rule,2005
Churna/Kwath churna	2 months	1 year
Gutika(varti gutti/pills)	1 year	2 years
Gutika/Tablet (contains Rasa, Uparasa, metalic Bhasma)	1 year	5 years
Vati(Tablet)	1 year	2 years
Rasausadhies	Older is better	No expiry date
Asava, Arista	Older is better	No expiry date
Avaleha	1 year	2 years
Guggulu	1 year	5 years
Mandura Lauha	Older is better	10 years
Ghrita	4 – 6 months	1 year and 6 months
Taila	4 – 6 months	2 years
Arka	1 year	1 year
Dravak/Lavan/ksara	1 year(ksara 1-5 years)	5 years
Lepa chrna	2 months	1 year
Lepa Malahara(ointments)/Liniments/Gels	2 months	2 years
Varti	1 year	2 years(one time use)
Ghana vati	1 year	2 years
Kupipakwa rsayan	Older is better	No expiry date
Parpati	Older is better	No expiry date
Pisti and Bhasma	Older is better	No expiry date
Bhasma of Swarna, Rajat, Louha, Mandura, Abhraka, Godanti, Shankha, etc.	Older is better	No expiry date
Bhasma of Naga, Vanga, Tamra.	Older is better	5 years
Syrup/Oral liquid	4 months upto 1 year	3 years
Paka/Granule	2 – 4 months	2 years
Dhoopan- Inhalers	6 months	2 years

Naga bhasma, Vanga bhasma and Tamra bhasma starts solidifying after 5 years. So, there is needed the repeatation 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 [3].

DISCUSSION

According to some experimental studies, the longer stability in recent Ayurvedic dosage forms is the gift of modern packaging technology and usage of stabilizers.

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 [6]. 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-smeared cloth was used as sealing material [7]. 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 [8]. 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, CO_2, other gases, moisture, micro-organisms and prevents 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 [8, 9, 10]. 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, envelops, strips, cartoons, boxes, drums, etc [8, 10,11].

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 hydroxyl toluene (BHT), butylated hydroxyl anisole (BHA), tocopherols, etc [12]. 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 semisolid 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 [12, 13]. 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 [14].

CONCLUSION

The main basis behind the development of different Ayurvedic dosage forms is supposed as to increase its therapeutic efficacy, shelf life and palatability. The shelf life period is calculated by using Arrhenius equation i.e. $\log k = \log z - E / 2.303 R \times 1/T$. It explains the effect of temperature on the rate constant k of a chemical reaction, z is the frequency factor, E is the energy of activation, R is the gas constant, T is the thermodynamic temperature [15].

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, silajatu, etc. as a bio active 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 [16]. Some of the reported studies have been discussed, in which attempts were made to establish the stability studies of some formulation using different packing and storage conditions. In first study Kutaki Churna used to study in two different packaging materials one was food grade polythene bag while the other was plastic container having Aluminium foil covering. The study was carried out up to 3 months at 40°C temperature and 75% relative humidity. The rate of degradation of drug

was more in polythene packet than the foil packing. So, it should be considered that modern shelf life of medicine is a gift of stabilizers and packaging technology [16].

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