Journal of Ayurveda & Holistic Medicine

www.jahm.co.in

eISSN-2321-1563

REVIEW ARTICLE OPEN ACCESS

SHELF LIFE OF AYURVEDIC DOSAGES FORM : PRESENT SCENARIO & NEED TO FOLLOW MODERN PARADIGM

RICHA OJHA[1] ANKIT KUMAR GUPTA[2] SANJAY KUMAR PANDEY[3]

Abstract

Shelf life of Ayurvedic dosages forms is mentioned after 13th century. From basic kalpana to derived kalpana shelf life varies from 3 hr to several years. Shelf life is a very important aspect of pharmaceutics, which depends upon packaging, storing, material to be used in packaging, excipients used in dosages forms and some other external aspects as like climatic condition of storage place and markets. Thanks to modern system of packaging, storing, transporting system and packaging material shelf life of Ayurvedic dosages forms enhanced. Government of India issued a first gazette notification in 2009 and revised gazette notification in 2016 for shelf life of Ayurvedic dosages forms. Ayurveda still has to adopt many aspect of modern paradigm of technical advancements and to cope up with markets demands to reach out the more customer bases and have a higher share as per its potential, development of new dosages forms are one of them. Some modern dosage forms are introduced in Ayurvedic system of medicine like tablets, capsules, sprays, eye drops, toothpaste, facewash etc. The guidance on *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* was published as Annex 2 in the World Health Organization (WHO) Technical Report Series, No. 953, 2009 (*1*).The aim of these regulatory guidelines is to outline the core stability.

Keywords: Saveerytavadhi, shelf life, stability, stability testing parameter

[1*]PG Scholar, [2]Lecturer, [3]Sanjay Kumar Pandey Dept. of Rasashastra and Bhaishjya Kalpana, Govt P.G. Ayurvedic College and hospital, Varanasi, INDIA

Corresponding Author Email id: nirjara.richa@gmail.com Access this article online: www.jahm.co.in

INTRODUCTION:

Ayurvedic dosage forms are gradually evolve with Ayurveda, from basic dosage forms like (swaras, kwath etc) to more stable derived dosages forms like (aasav, taila). Ayurvedic dosage forms can be classified into Solid dosage forms(like vati, pills, etc.), semisolid dosages forms(like avaleha,ghana etc.), liquid dosages forms(like aasava,arka,taila etc.), powder dosage forms(like bhasma, satva, mandoora, etc) [(1)]. Basic kalpana only can be prescribed in fresh condition because of their short shelf life, while derived formulation like asav, arishta, avaleha etc.,having comparatively more shelf life than basic formulations, can be prescribed throughout years .

In Ayurvedic context shelf life is known as Saveeryatavadhi, means time period during which the veerya of any drugs remains un-affected or the time period during which the potency of any drug is maximum[(2)]. Nowadays shelf life means the time period during which an API (active pharmaceutical ingredient) or FPP (finished pharmaceutical product) is expected to remain within the approved stability specification provided that it is stored under the condition defined on the container label[(3)].

Shelf life of a drug product is defined as the time at which the average API and FPP remain within an approved specification if stored under the condition in which stability was stablished[(4)]. Since 1979 the food & drug administration (FDA) has required that all prescription drug have a shelf life[(5)], or expiration date indicated directly on the container for any of the drug being sold to the market, it is compulsory to display the shelf life as per rule 161B of Drug and Cosmetic Rule 1945[(6)] .

Shelf life of ayurvedic dosages forms:

The classical Ayurvedic text which was written before 12th AD had not mentioned Saveeryatavadhi (shelf life), after 12th AD Ayurveda scholars like Vangasen, Sharngdhar and Yogratnakar clearly mentioned saveeryatavadhi of ayurvedic dosage form**.** Yogratnakar mentioned shelf life of swaras, kalka, kwath is 3 hour, anjana has 3 months, churna have 3 month. Shelf life of some other Ayurvedic formulation as per classical texts of Ayurveda is mentioned as follows[(7)].

Table 1: Saviryta Avadhi of different Ayurvedic dosage forms as per classics

Sr.No	Dosage Form	Saviryta Avadhi		
		According to Vanga Sen	According to Sharangdhar	According to Yogaratnakar
1.	Kwatha (decoction)	-----	---	03 hours

2.	Kalka (paste)	---	---	03 hours
3.	Swarasa(expressed juice)	---	---	03 hours
4.	Anjana (collyrium)	---	---	03 months
5.	Churna (Powder)	---	02 months	03 months
6.	Vati (pills)	---	12 months	---
7.	Guda/Avaleha (electuary)	12 months	12 months	06 months
8.	Ghrita & Taila (Oil & Fat based preparation)	06 months	16 months	12 months
9.	Asava (Alcoholic preparation)	---	Long term stability	---
10.	Dhatu (Metallic preparation)	---	Long term stability	---
11.	Rasa (Mercurial preparation)	---	Long term stability	---

In present time shelf life of some Ayurvedic dosage forms are re-established in Gazette of Government of India 2016. According to gazette notification anjana has 1 year, churna has 2 years, gutika or vati containing kasthaushadhi along with rasa/uprasa/bhasma/guggulu has 5 years, gutika or vati containing only kasthaushadhi has 3 years, gutika or vati containing only rasa/uprasa/bhasma except Nag/Vang and Tamra bhasma has 10 years of shelf life. Other dosage forms shelf life mentioned as follows[8].

Table no :-2 According to gazzet of governament of india 2016 shelf life of .ayurvedic dosages forms are as follows:

Sr no	Dosages form	Shelf life or date of expiry with effect from the date of Manufacture
1	Anjana made from Kasthaushadhi, Arka, Netrabindu.	1 year
2	Anjana made from Kasthaushadhi along with Rasa/Uprasa/Bhasma, Churna, Kwatha Churna, Lepa Churna, Danta Manjan (Churna), Dhoopan, Ghrita, Karna/ Nasabindu, Sattva (derived from medicinal plant), Shveta parpati , Varti,	2 years
3	Anjana made only from Rasa/Uprasa/Bhasma ,	3 years

	Avaleha, Khanda, Paka, Guda ,Sharkar/ Panak/Sharbat, Taila, Pravahi Kwatha , Gutika or Vati containing only Kasthaushadhi(including Lepa Gutika and Ghan Vati) and Malahar .	
4	Dravaka, Lavana, Kshara, Guggulu, Gutika or Vati containing Kasthaushadhi along with Ras / Uprasa / Bhasma/Guggulu(including Lepa Gutika and Ghan vati), Naga Bhasma, Vanga Bhasma and Tamra Bhasma, Rasayoga Containing Rasa / Uprasa/ Bhasma along with Kasthaushadhi/Guggulu.	5 years
5	Asava Arista, Gutika /vati containing only Rasa/Uprasa/Bhasma (except Naga,Vanga,and Tamra Bhasma), Kupipakva Rasayana, Mandura-Lauha, Parpti, Pishti and Bhasma except Naga,vanga, and Tamra Bhasma, Rasayoga Containing only Rasa /Uprasa / Bhasma except Naga, Vanga and Tamra Bhasma	10 years

It means the potency of the drugs mentioned above remain intact at that time period. As we can see the shelf life of churna have 2 month of stability but thanks to modern packaging techniques churna has 2 years of shelf life, like churna some other packaged drugs, foods etc have more than a year of shelf life so we can say packaging and storage plays very important role in stability of dosages forms. Acharya Charak in Kalpa Sthan clearly mentioned that the potency of drug increased by proper use of Desh, Kal, Guna, Bhajan (store room)[9] . In Ayurveda there are number of storage media for raw drugs and prepared drugs are used in classical and traditional methods, like Ghrit Bhavit Patra for Lauhadi rasayan ,Swarna Patra or Rajat Patra for Amlak Ghrit , Lauha Patra for Aamlkayas Bramh Rasayan. Some other storage media mentioned as follows.

Table no:-3 Description of different storage media in ayurveda

Sr.No.	Dosages forms	Storages media	Reference
1.	Lauhadi Rasayan	Ghrit Bhavit kumbh	Cha. Chi. 1/3/18
2.	Dwitiya Bramhrasayan	Ghrit Bhavit Kumbh placed in a pit full of Rakh(ashes)	Cha. Chi. 1/1/58
3.	Aamlak ghrit	Swarna patra or Rajat patra or Ghrit Bhavit Mritkalash	Cha. Chi. 1/2/4
4.	Aamlak churna	kept in Ghrit Bhavit Mritpatra and placed in Ashes pit in Pravrit ritu and excavate in Sharad ritu	Cha. Chi. 1//2/8

5.	Vidangavaleh	put in Ghrit Bhavit patra and in Pravrit ritu placed in pit full of ashes and excavate in Varsha ritu	Cha. Chi. 1/2/9
6.	bhallatak das yog	in summer season bhallatak fruits placed in dhanya or mas rashi	Cha. Chi.1/2/13
7.	Aamlkayas Bramharasayan	Lauh patra	Cha. Chi. 1/3/3
8.	Kanakkshiri Taila	Katukaalabu	Cha. Chi. 7/116
9.	Sidhma lepa	Tamra patra	Cha. Chi. 1/117
10.	Sahcharadi taila	shilapatra or meshshring	Cha.Chi.26/265
11.	Kantkarya valeha	Mritpatra	Sha.Samhita Madhya khanda 8/9

Factors affecting shelf life:- Shelf life is directly depends on stability of drugs, and stability is directly affected by light, air, humidity, heat, type of ingredients of drugs , nature of excipients, process of manufacture ,type of container used in storage, and chemical reactions like oxidation , reduction, hydrolysis. So packaging is very important part of pharmaceuticals. A packaging material should be compatible with the ingredient of drugs. So NMPB prescribed different type of storage material like gunny bags, jute bags, woven sacks, airtight plastic drums etc as follows-

Table no: 4 According to national medicinal plant board packaging materials are as follows[(10)]:-

Sr. No.	Type of the Drugs Product	Packaging Options
1.	Woody in nature – roots, stem, wood, woody bark etc.	1.Gunny Bag 2. Jute Bags 3. Woven Sacks
2.	Annual whole herbs, creepers, twiners, leaves, etc.	1. Woven sacks with low density liner 2. Jute bags
3.	Fleshy materials-fleshy rhizomes (e.g. Shatavari), fruit rinds (Kokum butter) of flowers (Mahua)	1. Jute bags with high gauge polyethylene liners 2. Woven sacks with high gauge polyethylene liners
4.	Delicate flowers and floral parts – Anthers, Stigma, Petals etc.	1. Corrugated box with polyethylene liners 2. Card-board box with woven sacks
5.	Gums and resins	1. Air-tight Plastic drums 2. Corrugated box with polyethylene liners
6.	Aromatic plant produces	1. Air tight High Density Polyethylene (HDPE) containers 2. Fiber board drums wit polyethylene liners

Beside packaging storage also plays very important role in stability. According to goods storage practices mentioned in para 1.1(F) of schedule T of drugs and cosmetic Rules-1945, stores should have proper ventilation and shall be free from dampness. It should provide independent adequate space for storage of different types of material, such as raw material and finished products. Para 1.1(F) of Drugs & Cosmetics Rules – 1945 describes the storage condition for Raw Material (as like of metallic origin, mineral origin ,animal source etc) , Packaging Material, & finished goods in sub para (A),(B) & (C) thereof[11].

Calculation of stability:- stability testing is a very important step of drug development. The final pharmaceutical products will undergo with various types of physical/chemical changes as like consistency, density, moisture contents of drugs, oxidation etc with the time. The stability test is required to determine that under what circumstances the properties of pharmaceutical components will deteriorate[12].

A) **Real time stability testing** is done for the long duration so that the degradation of product can be detect even if that product stored under recommended condition. The product is stored in its actual packaging material and storage condition and data is collected at a set interval to measures the physical and chemical property of drugs. The existing set of data for reference batch must be accounted and the output is studied in the light of same.

B) **Accelerated stability Testing**:- this study is performed under the stressed condition, the actual stability will be projected based upon the finding of the same. When the activation energy is known, the degradation rate at low temperatures may be projected from those observed at "stress" temperatures

•The stress tests used in the current International Conference on Harmonization (ICH) guideline (e.g., 40% for products to be stored at controlled room temperature) were developed from a model that assumes energy of activation of about 83 kJ per mole

C) **Retained Sample Stability Test:-** As per the established practices stability sample out of every 50 batches in a year is retained for the study on the stability parameter. This selection is done randomly and measures for stability will be taken on every set time of interval, e.g. for 5 years of self life measures will be taken on 03,06,09,12,18,24,36,48, & 60 months. This method is known as the constant interval method.

D) **Cyclic Temperature Stress Testing**:- The test is conducted in the same situation in which the actual products going to store on daily basis. The temperature variation is set to follow the

diurnal cycle of a climatic condition. The degradation in the product active component will study. The projection of stability is prepared based on the finding data.

WHO has classified the whole world in four climatic zones for the purpose of stability testing. The temperature and humidity parameter is set during the study period based upon the climatic zone where product is going to be marketed. WHO established testing parameter for prepared dosage forms according to which tablet, capsules, oral suspensions, nasal sprays, topical, ophthalmic and otic solutions etc have different testing parameters. like tablets have dissolution, disintegration, water content and hardness etc, capsules first categorised into hard gelatine capsule and soft gelatine capsules, hard gelatine capsule have brittleness, dissolution, disintegration, parameters and soft gelatine capsules have dissolution, disintegration, level of microbial contamination ,PH, leakage and pellicle formation[13]. Some other dosages forms testing parameters are listed below in table.

Table no :-5 Testing parameter for prepared dosage forms according to WHO

Dosages forms	Testing parameters
Tablets	Dissolution, disintegration, water content and hardness/friability. Etc
Capsule	1. hard gelatin capsules: brittleness, dissolution, disintegration, water content and level of microbial contamination; 2. soft gelatin capsules: dissolution, disintegration, level of microbial contamination, pH, leakage and pellicle formation
Powders and granules for oral solution or suspension	Water content and reconstitution time.
Nasal sprays: solutions and suspensions	Clarity (for solution), level of microbial contamination, pH, particulate matter,unit spray medication content uniformity, number of actuations meeting unit spray content uniformity per container, droplet and/or particle size distribution,weight loss, pump delivery, microscopic evaluation (for suspensions), foreign particulate matter and extractables/leachables from plastic and elastomeric components of the container, closure and pump.
Topical, ophthalmic and otic preparations	Included in this broad category are ointments, creams, lotions, pastes, gels,solutions, eye drops and cutaneous sprays. ■■ Topical preparations should be evaluated for clarity, homogeneity,

	pH, suspendability (for lotions), consistency, viscosity, particle size distribution (for suspensions, when feasible), level of microbial contamination/sterility and weight loss (when appropriate). ■■ Evaluation of ophthalmic or otic products (e.g. creams, ointments, solutions and suspensions) should include the following additional attributes: sterility, particulate matter and extractable volume. ■■ Evaluation of cutaneous sprays should include: pressure, weight loss, net weight dispensed, delivery rate, level of microbial contamination, spray pattern, water content and particle size distribution (for suspensions

DISCUSSION:

Shelf life of a dosages forms means the time period up to which active principal of that dosages forms remain stable. In terms of Ayurveda shelf life is known as saveerytavadhi. Saveeryatavadhi of Ayurvedic dosages forms are comes in light after 12^{th} century when vangsena, yogaratnakar and sharangdhar written about shelf life in their textbooks. But they have different opinion on shelf life of different dosages forms, like shelf life of ghrit and taila according to vangsen is 6 months, according to sharangdhar is 16 month and according to yogratnakar is 12 months so these differences create a confusion. we can assume that these differences is may be due to material used in formation of taila/ghrita, due to storage condition, or due to packaging material. In present days due to advancement in packaging and storage condition shelf life of ghrita/taila is 3 years.

U.R.S.R.K Senarathna and Bishwajyoti Patgiri in their research “shelf life studies conducted on ayurvedic medicines- a reviw” tried to establish some Ayurvedic dosages forms shelf life. According to their study Rasayan Churna has 2 years 9 months, Constac plus powder has 2 years, Hutabhugadi Churana has 11.41

months of shelf life. Other dosages form's evaluated shelf life mentioned below.

Table no:-6 shelf life evalution of different ayurvedic yogas.

Sr. No.	Dosages forms	Shelf life
1.	Rasayana churna.	2 years 0.9 month
2.	constac plus powder, Shirishavaleha prepaired by kanji.	2 years
3.	Hutabhugadi churna.	11.41 month
4.	Amritamehari churna, Kamsaharitaki avaleha.	1 year and 6 month
5.	Hingwashtak churna.	At least for 6 months
6.	Dasmula kwath churna, Ajamoda arka.	4 months
7.	Hridaya yoga churna, Nishamalaki churna.	3 years and 7 months
8.	Kamsharitaki granules .	2 years and 3 months
9.	Shirsha ashwagandhadi avaleha. (metallic component present)	8 years and 7 months
10.	Trivrit avaleha.	1 year and 11 months
11.	Shirishavaleha prepared by water, Kumkumadi ghrita prepared using kesara, Kumkumadi ghrita prepared using Nagakesara.	1 year and 4 months
12.	Bramhi ghrita .	At least for 6 months
13.	Laghu sutashekhar rasa.	2 years and 8 months

CONCLUSION:

Several factors attributed the quality and acceptability of any dosages forms and shelf life is one amongst these. ayurvedic classic has clearly include this and thoroughly described it in terms of there organoleptic charecters as well as time period. Specific storage media is well elaborated in classics. In recent development shelf life of ayurvedic drug is notified by government of India which is given in The Drug and Cosmetic Rule. However packaging and storage conditions are not specifically given according to nature of drug as it is given in relation to modern drug which also contribute the stability of drug. National Medicinal Plant Board has specified packaging material according to nature of plant parts to be packed. Though in the preview of the Drugs and cosmetics Rule it is mandatory to display the expiry date of ayurvedic medicine but now it is the time that storage conditions of these medicines should also be specified.

REFERENCES

1) Shubhajit ghosh et al, a literature review on various ayurveda dosage forms, research and reviews: A journal of Ayurvedic Science,Yog and Naturopathy.ISSN:2395-6682(online),volume 5,issue 3,www.stmjournals.com

2) Sastri P, *Sharangadhara Samhita* with commentary,(Choukhambha Orientalia Publication, Varanasi), 2002, 13.
3) Dekker T, *Stability Studies (emphasis on FPPs)*, Workshop on GMP and Quality Assurance of Multisource Tuberculosis Medicines, Kuala Lumpur – Malaysia, 21-25 February, 2005.
4) ANNEX 10:stability testing of active pharmaceutical ingredient and finished pharmaceutical products:WHO expert committe on specification for pharmaceutical preparation:fifty second report.
5) Robert capen,et all on the shelf life of pharmaceutical products,AAPSPharmaSciTech. 20212 sep;13(3):911-918,published on line 2012 june 23.doi:10.1208/s12249-012-9815-2, PMCID:PMC3429690 ,PMID:22729779
6) ANNEXURE 1 of CCRAS MoA,GoI,Central Guidelines fo rDrug Development of Ayurvedic Formulations, Volume-1,Rule 161-B of G.S.R 789(E).
7) Gupta Ankit et al; Shelf Life of Ayurvedic dosages forms –Traditional view ,Current status and prospective need; Indian Journal of Traditional Knowledge vol.10(4);October 2011,pp672-677.
8) Table for shelf life of ayurvedic drugs under Rule 161(B)(8) of Drug and Cosmetic Rule 1945.
9) Charak Samhita,Vidyotani hindi comentry,Pt kashinath sastri and Dr Gorakh Natha Chaturvedi,part 2,chaukhabha Bharati publication,kalpa sthan first chapter.
10) Annexure C of Standard for Good Field Collection practices of Medicinal Plants;national Medicinal Plants Board ;Department of AYUSH,Ministry of Health and Family Welfare, Gov. Of India
11) Para 1.1(F) ((A),(B),(C)) of G.M.P under schedule T of Drug & Cosmetic Rule 1945.
12) Sanjay Bajaj et al ; stability Testing of Pharmaceutical products ;Journal of applied Pharmaceutical Sciences;journal of Applied Pharamceutical sciences 02(03);2012:129-138
13) .Appendix 1:ANNEX 10: stability testing of active pharmaceutical ingredients and finished pharmaceutical products :WHO expert committe on specification for pharmaceutical preparation:fifty second report.
14) U.R.S.R.k. Senarathna et al: shelf lif studies conducted on ayurvedic medicine- A reviw ;Int J Ayu Pharm Chem ; e- ISSN 2350-0204.

Cite this article as:

Richa Ojha, Ankit Kumar Gupta, Sanjay Kumar Pandey. Shelf life of Ayurvedic dosages form: Present Scenario & Need to follow Modern Paradigm, *J of Ayurveda and Hol Med (JAHM)*.2020; 8(6):39-48

Source of support: Nil

Conflict of interest: None Declared