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Shelf life of Ayurvedic Formulations in Ayurveda Classics and Present Scenario

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ABSTRACT

The most common myth regarding ayurvedic medicine is that these medicines don't have any no expiry date but in reality, it is not true, Ayurvedic medicines do have shelf life. During Samhita period there is no proper explanation regarding the *Saviryata Avadhi* only explanation found was regarding the methods of collection and storage of raw materials. Scholars of Medieval period mentioned shelf life of primary *kalpanas* for some hours and no expiry for the *Bhasma* and *Asava arishta* is mentioned. These Guidelines and regulations are followed for a long period i.e. over the centuries. In present due to commercialization many modifications and advancement happened in the field of manufacturing of medicines hence there was an urgent need to reconsider the guidelines of Shelf life to be re-considered. Hence Pharmacopoeial committees along with CCRAS and WHO laid down new Shelf life regulations for the whole system of Ayurvedic Formulations. In this paper the ancient guidelines are discussed alongside of the Present updated parameters of shelf life.

KEYWORDS

Saviryata Avadhi, Shelf life, Ayurvedic formulation, updates



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INTRODUCTION

Ayurveda defined various formulations in *Bhaishajya Kalpana* (dosage form). they are *Svarasa*, *Kalka*, *Shruta/kwath*, *Sheeta/Hima*, *Phanta* is basic dosage forms and few other forms like *Churna*, *Vati*, *Ghirta-Tail*, *Asava/ Arishta* considered as secondary form derived from primary dosage forms. The *Saviryata Avadhi* (Shelf life) of basic form is considered as around *1 Prahar* (hrs) (Table 3). while secondary formulations prepared out of these Primary formulations are of longer shelf life. *Rasashastra* branch of the medicine manufacturing deals with the preparation of the medicines out of metals and minerals which are meant to have faster efficacy and longer shelf life compared to herbal formulations. Their shelf life is very long but not countable in specific time After long time Scholars describe time period of primary forms expiration date potency of drugs increase therapeutic value and after lose the potency medicinal properties or active ingredient's available in drugs after losing therapeutic value will also decrease and it is not beneficial for people. Now the time is changing the new equipment's, tools, packing materials, preservatives are available so estimated time duration forms are varying.

SHELF LIFE OF AYURVEDIC DRUGS MENTIONED IN TEXTS

The Concept of *Virya* (potency) of the various dosage form of ayurvedic is *Saviryata Avadhi* (Time period of Active properties) which means that time period of active potency in drug.in classic *Charak Samhita* & *Shushrut Samhita* mentioned packing and storing of fresh & old medicinal materials & therapeutic uses in which its properties (Appearance, Smell, taste etc) are remains unaffected conditions^{1,2}. but not mentioned how long time. After 13th century AD, many Authentic texts like *Vanga Sena*, *Sharangdhar Samhita* and *Yogratnakar*, they mentioned the shelf life of different doasage form specifically with time duration of Aushadhies (medicines).

According to *Sharangdhar Samhita*³:

गुणहीनं भवेद् वर्षादूर्ध्वं तादुपमौषधम् ||

मासाद्भयात् तथा चूर्णं हीन्विर्यत्वमाप्नुयात् |

हीनत्वं गुटिकालेहौ लभेते वत्सरात् परम् ||

हीनाः स्युघृततैलाद्याश्चतुर्मासाधिकात् तथा |

औषध्यो लघुपाका स्युनिर्वीर्या वत्सरात् परम् ||

पुराणाः स्युर्गुणैर्युक्ता आसवा धातवो रसाः ||

शा.स.पू.ख./१/५४-५६

All the *Aushadh Drvaya/Aushadha Kalpana* lose potency after one-year time period. Or *Laghu paaki Aushadh* will lose their potency after one year. *Panchvidha Kashaya Kalpana* (five basic dosage form)



and *Upkalapana* (Secondary dosage form) are for instant use i.e. soon after preparation they are to be utilized.

In Text of *Sarangdhar*³.

Table 1 In texts of *Vanga Sen*⁴

S.No	Dosage form	Time duration
1	<i>Churna</i>	2 months
2	<i>Avaleha</i>	1 year
3	<i>Vati/Gutika</i>	1 year
4	<i>Asav/Arishta</i>	No Expiry
5	<i>Dhatu/Rasa</i>	No expiry
6	<i>Laghu paaki Aushadh</i>	1 year
7	<i>Ghrita/Tail</i>	16 months

Table 2 In texts of *Yogaratanakar*⁵

S.No	Dosage Form	Time Duration
1	<i>Avleha</i>	1 year

Table 4

S.No	Different Dosage form of Ayurveda	Shelf life Ayurvedic medicine	Shelf life Ayurvedic medicine	Shelf life Ayurvedic medicine
		Rules,2005 ⁶	2009 Pre-revised Rule G.S.R 764(E)	2016 Pre-revised Rule G.S. R789(E)
1	<i>Churna, Kwath Churna</i>	1 years	2 Years	2 years
2	<i>Gutika (Vati, pills, tablets) with kashth Aushadhi</i>	2 years	3 years	3 years
3	<i>Rasaushadhis</i>	No expiry	No expiry	10 years
4	<i>Asava -Arishta</i>	No expiry	No expiry	10 years
5	<i>Avaleha</i>	2 years	3 years	3 years (includes <i>khanda, paka, guda</i> also)
6	<i>Guggulu</i>	5 years	5 years	5 years
7	<i>Mandura lauha</i>	10 years	10 years	10 years
8	<i>Ghrita</i>	1 and half years	2 years	2 years
9	<i>Taila</i>	2 years	3 years	3 years
10	<i>Arka</i>	1 year	1 years	1 years
11	<i>Dravak Lavana, kshara</i>	5 years	5 years	5 years
12	<i>Lepa churna</i>	1 years	3 years	2 years
13	<i>Dant manjan Powder & Paste</i>	-	2 years	2 years
14	<i>Lepa gutika</i>	-	3 years	5 years
15	<i>Lepa malhar (Ointment), Lotion, Gel, Creams</i>	2 years	3 years	<i>Malhar-</i> 3years
16	<i>Varti</i>	2 years onetime use	2 years (1times)	2 years
17	<i>Ghana vati</i>	2 years	3 years	5 years
18	<i>Kupipakva rasayan</i>	No expiry date	No expiry Date	10 years
19	<i>Parpati</i>	No expiry date	No expiry Date	10 years

2	<i>Gutika</i>	1 year
3	<i>Ghrita/ Taila</i>	6 months

Table 3

S.No	Dosage Form	Time Duration
1	<i>Svaras</i>	3 hours
2	<i>Kalka</i>	3 hours
3	<i>Kwath</i>	3 hours
4	<i>Sheet (Hima)</i>	3 hours
5	<i>Phant</i>	3 hours
6	<i>Churna</i>	3 months
7	<i>Avleha</i>	6 months
8	<i>Gutika</i>	6 months
9	<i>Ghrita/ Tail</i>	1 year
10	<i>Anjana</i>	3 months

Drugs & Cosmetic Act 1945, Department of AYUSH under Ministry of Health & Family Welfare Part -II, Section-3, Sub Section (1) of Gazette of India^{6,7,8,9}.



20	<i>Sveta Parpati</i>	2 years	2 years	2 years
21	<i>Pisti & Bhasma</i>	No expiry date	No expiry Date	10 years
22	<i>Svarna , rajat godanti etc</i>	No expiry date	No expiry Date	10 years
23	<i>Naga bhasma, Vanga , tamra Bhasma</i>	5 years	5 years	5 years
24	Capsules (Soft gelatine) For <i>Kasth Aushadhi</i>	2 years	3 years	3years
25	Capsules (Hard gelatine) containing <i>kasth aushadhi</i> with <i>Rasa bhasma</i>	3years	5 years	3years
26	Syrup/liquid oral	3 years	3 years	3years
27	Ear/ Nasal drop	2 years	2 years	2 years
28	<i>Khand/Granules /paak</i>	2 years	3 years	2 years
29	<i>Dhoopans -Inhaller</i>	2 years	2 years	2years
30	<i>Pravahi kwath</i> with preservatives	-	3 years	3 years
31	<i>Anjan</i>			
	(A) With <i>kasth Aushadh</i>	-	-	1 years
	(B) With <i>kasth Aushadh, Rasa, Uprasa</i>	-	-	2 years
	(C) Only <i>Bhasma</i>	-	-	3 years
32	<i>Gutika</i> or <i>Vati</i>		-	
	(A) Containing <i>kasthaushadhi</i> with <i>Rasa /Uprasa bhasma/guggulu</i> (including <i>lepa & Ghan lepa</i>)	5 years		5 years
	(B) Only <i>kasth aushadhi</i> with (includes <i>lepa gutika</i> and <i>Ghan lepa</i>)		-	3 years
	(C) Only <i>rasa</i> not <i>naga, vanga ras/ uprasa</i> except <i>Naga, Vanga & Tamra</i>	2 years		
			-	10 years
33	<i>Rasayoga</i>			
	(A) Only <i>Rasa/upras/bhasma</i> except <i>Naga/Vanga & Tamra</i>	-	-	10 years
	(B) <i>Rasa/uprasa/bhasma</i> with <i>kasth aushadhi/Guggulu</i>	-	-	5 years
34	<i>Satva</i>	2 years	-	2 years
35	<i>Shakar/panak/Sharbat</i>	-	-	3 years

Anonymous,2005, The Gazette of India,
Extraordinary part -II, section 3

Anonymous,2009, The Gazette of India,
Extraordinary part -II, section 3

Anonymous,2016, The Gazette of India,
Extraordinary part -II, section 3

Factors Affecting for loosing potency:¹⁰

1. Humidity
2. Temperature
3. Seasonal
4. Dust

5. Infection by microorganism

6. Shelf life degeneration evaporation
hygroscopic nature

7. Light

DISCUSSION

The *Saviryta Avadhi* is said to be a most important in *Bhaishjya kalapna* the shelf life of each and every drug will differ according to many factors & it will depend upon the climate, humidity, packing etc¹⁰.



- After shelf life the drug will lost its potency.
- In Ancient time Ayurvedic dosage is limited and present time many different types of dosage form is included.
- In Ancient time *Vaidya's* used to prepare less amount of medicine for their own patient according to their requirement, but in present days pharmaceutical companies prepare medicines in larger scale or in bulk because of increased demand and requirement. Globalization of Ayurveda tend to export the medicines at International level.
- That's why Ayurvedic medicines standardization are needed, by proper manufacture, proper use of preservatives according to drug requirement and good packaging materials¹¹.
- Packing of drugs in earlier days were not so advanced as in present days where the packing materials are of advanced and of high-quality owing to the preservation of the potency of the formulations packed.
- Texts of Ayurveda recommended for *Aaushdh* and *Ahara kalpanas* and their *Saviryta Avadhi* (their expiry date is period or which they can retain potency).
- Nowadays, the ayurvedic industries are also utilizing these technologies for the packaging and storage of their formulations

which ultimately enhances the shelf life of the products.

- After the development and incorporation of these techniques, there is a need arises for the study and revision of the shelf life of ayurvedic formulations as during those periods¹¹.
- The drugs were stored in earthen pot or cloths etc which are not as much viable to stabilize the qualities of the drug for longer period¹¹.
- In current scenario Ayurvedic Pharma industries used preservatives for juice /*swaras* or *kwath* / *kashayam* etc for long period (6 months).
- Some changes in prevised shelf life in 2005 & 2009 no time duration of metallic preparation but in 2016 mention expiration is metallic or Herbo-metallic preparation expiry date 5 to 10 years.
- Some other changes like in *Naga* (Lead), *Tamra* & *Vanga* have 5 years but they are Extended for 2 - 3 years given 2-3 Puta (incineration) for therapeutic use.

CONCLUSION

The shelf life is very important concept in Ayurvedic dosage form. New techniques are used to increase longevity of Primary dosage form, because of good packaging and proper use of preservatives. In Ancient time limited form of medicines were used



and *Vaidya's* prepare medicine by own to their patients. And now medicines are preparing in bulk are more potent because of all these modern techniques. Proprietary medicines in new form like soft / hard gelatine, capsules, cream, jelly, shampoo, emulsion, granules etc. which will enhance its shelf life.



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