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Shelf Life of Ayurvedic Dosage Forms in Regulatory Perspectives

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Abstract Ayurveda is an ancient (since 1000 B.C.) system of traditional medicine in India. It is not only practised in India even practiced globally as a complementary and alternative medicine system. Ayurveda defined enormous formulations belongs to different *Bheshaj Kalpana* (dosage forms) out of which *Svarasa* (juice), *Kalka* (paste), *Shruta/Kvatha* (decoction), *Sheeta/Hima* (cold infusion) and *Phanta* (hot infusion) can be considered as basic/primary dosage forms and few other dosage forms e.g. *Churna* (powder), *Vati* (tablet/pills), *Tail/Ghrita* (medicated Oils/Clarified butter), *Asava* and *Arishta* (self-generated alcoholic preparations) and *Avaleha* (electuary/semisolid confectionary) considered as secondary dosage forms derived from primary dosage forms. The *Saviryta Avadhi* (shelf life) of the basic dosage forms are considered as 03 hrs while the shelf life of derived dosage forms is varied as the later mentioned formulations comprises complicated specified Ayurvedic medicine processing and inclusion of natural preservatives also. In the current scenario, the amendment of Rule No. 161-B of Drugs and Cosmetic Act 1940, specify the maximum shelf life or date of expiry; unless otherwise determined on the basis of scientific data of an Ayurveda medicine defined under clause (a) of section 3 of the Act. This rule also stated that the Ayurvedic medicine defined under clause (h) of section 3 of the Drugs and Cosmetic Act 1940, the scientific data based shelf life based on the Real-time stability studies of medicines should be derived in accordance with the guidelines prescribed in Ayurvedic Pharmacopeia of India Part I, Vol III.
Keywords *Saviryta Avadhi (shelf life); dosage forms; Ayurvedic Pharmacopoeia of India (API); Drugs and Cosmetic Act 1940 (D & C Act 1940); Ayurvedic; Siddha or Unani (ASU)*

1. Introduction

The Ayurveda system of medicine primarily inscribe five basic dosage forms i.e. *Svarasa* (juice), *Kalka* (paste), *Shruta/Kvatha* (decoction), *Sheeta/Hima* (cold infusion) and *Phanta* (hot infusion) involving simple pharmaceutical processing, on the basis to be prescribed to different *Prakriti* (Natural constitution) of patient and severity of the disease. These medicines are generally prepared by the physicians/patient and more specific for the patient's diseased condition as well;

these preparations are difficult to intake because of its palatability. Also, those preparations are perished within very short period i.e. within 03 hours, so have to be prepared frequently since these preparations generally derived from fresh forms of the different herbs and are semisolid/liquid in nature. While subsequently secondary derived dosage forms e.g. *Churna* (powder), *Vati* (tablet/pills), *Tail/Ghrita* (medicated Oils) *Asava* and *Arishta* (self-generated alcoholic preparations) and *Avaleha* (electuary/semisolid confectionary) were evolved, these are generally poly-herbal in nature and encompasses the more specific Ayurvedic pharmaceutical processing & incorporation of natural preservatives contributes to possessing longer shelf life and these preparations having better palatability, easy to administration in the weak/young/child/female patients. Later on, *Rasa Shastra* scholars inculcate *Bhasma* (incinerated Metals/minerals), *Rasayoga* (formulations containing Parad (mercury) or its compounds/ *Bhasma* of different metals/minerals/precious stone/animal products with/or without herbs) which are more potent, fast acting and used in the lesser dose and comprises the very long shelf life also.

2. Concept and Shelf Life of Ayurvedic Dosage Forms

The concept of *Virya* (Potency) of the various Ayurvedic dosage forms explained in various Ayurvedic texts and signify that the *Saviryta avadhi* (time period of the Potency or Shelf life) is the specified period during which the *Virya* (Potency) of the drug remains or it is the time limits by the which the drug reduces its original potency up to some extent and should be recommended for prescription before lapse of that specified period of time (Sastri, K.N. & Chaturvedi, G.N., 1969; Charaka Samhita with commentary & Acharya Jadhavji Trikamji Vaidya, 1980; Susruta Samhita with commentary). The main factors affecting the Shelf life are derivation of the drug, dosage forms, environmental factors (humidity, temperature, light), microbial contamination, storage conditions & packaging system etc.

Table 1: *Shelf life of various Ayurvedic Dosage forms at a glance as referred in Ayurvedic Texts*

S.N.	Ayurvedic Dosage forms	Ayurvedic Texts		
		Sarangdhara Samhita [a]	***Vanga Sen*** [b]	***Yogaratnakar*** [c]
1.	*Svarasa*	-	-	01 *Prahar* (3hrs)
2.	*Kalka*	-	-	01 *Prahar* (3hrs)
3.	*Shruta/ Kwatha*	-	-	01 *Prahar* (3hrs)
4.	*Sheeta/Hima*	-	-	-
5.	*Phanta*	-	-	-
6.	Churna	02 months	-	3 months
7.	Vati	12 months	-	-
8.	Guda/Avaleha	12 months	12 months	06 months
9.	Ghrita & Taila	16 months	06 months	12 months
10.	Asava (Arishta also)	Infinite (or may be more potent as gets older)	-	-
11.	Dhatu	-do-	-	-
12.	Rasa	-do-	-	-
13.	Anjana	-	-	3 months

[a] Sastri Parshuram, 1983, The Sharangadhara Samhita with commentary
[b] Rai Rajeev Kumar, 1983, Vangasen
[c] Shastri Lakshmipati, 1973, Yogaratnakar

3. Current Scenario of the Shelf Life of Ayurvedic Medicine

Till 2009, Rule No. 161, of the D & C Act, which was dealt with the rules applicable for the Labelling, Packing and limit of alcohol for the ASU medicine, did not obligatory specify to declare the Shelf life of the ASU medicine on the label of the product; only date of manufacture (For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue) is sufficient with the other mandatory requirement like name of the product, licence no., batch no., reference of the product, true list of the ingredients etc.

In the year 2009 the Department of AYUSH (Now Ministry of AYUSH) under Ministry of Health and Family vide G. S. R. 764 (E) dated 15th Oct. 2009 (Anonymous, 2009, The Gazette of India, Extraordinary Part-II, Section 3), incorporates the Rule no. 161-B referring the shelf life of the ASU medicine, in the Drugs and Cosmetic Act 1940 (D & C act 1940) and Rules made thereunder, which is now further revised vide G. S. R. No. 789(E), dated 12th August, 2016 2009 (Anonymous, 2016, The Gazette of India, Extraordinary Part-II, Section 3) by the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (Ministry of AYUSH), New Delhi and amend the Rule No. 161-B of D & C act 1940 and Rules 1945, applicable for the rules for shelf life of Ayurvedic, Siddha and Unani drugs. The focal points are as follows:

1: (1) These Rules may be called the Drugs and Cosmetics (5th Amendment) Rules, 2016.
(2) They shall come into force on the date of their publication in the Official Gazette.

2: In the Drugs and Cosmetics Rules, 1945, for rule 161-B the following rule shall be substituted, namely:-

"**161-B. Shelf life or date of expiry of medicines**

(1) The date of expiry of Ayurvedic, Siddha or Unani (ASU) medicines shall be conspicuously displayed on the label of container or package of ASU medicine, as the case may be and after the said date of expiry, no medicine shall be marketed, sold, distributed or consumable.
Provided that this rule shall apply to ASU medicines seeking licence or renewal of licence for manufacturing after the date of notification of the rules.
Provided also that this rule shall not be applicable to the ASU medicines manufactured and marketed prior to the date of this notification.

(2) Every person applying for licence or renewal of licence for the manufacturing of ASU medicines defined under clause (h) of section 3 of the Act (i.e. patent & proprietary ASU medicines), shall submit to the State Licensing Authority scientific data based shelf life or date of expiry of the medicine based on the Real-time stability studies of medicines in accordance with the guidelines prescribed in the Ayurvedic Pharmacopoeia of India (API).
Provided that this sub-rule shall be applicable after three years from the date of notification of the rules.

(3) The guidelines regarding stability studies as prescribed in the API, Part-I, Volume-VIII shall be applicable to all the medicines of ASU.

(4) The State Licensing Authority shall, before granting license or renewal of license for an ASU medicine, ensure validity of the data submitted by the manufacturer in support of the claimed shelf-life of that medicine.

(5) The State Licensing Authority may at any time direct the manufacturer to provide the samples of the medicine and any other related information; and may share it with the

Pharmacopoeial Laboratory for Indian Medicine (PLIM), Ghaziabad for analysis or independent validation.

(6) Where the manufacturer fails to comply with direction of the State Licensing Authority under sub-rule (5), the license for the manufacturing of the medicine shall be liable for suspension after giving a reasonable opportunity of being heard.

(7) Any person aggrieved by an order passed by the State Licensing Authority under sub-rule (6), may within sixty days of such order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as is considered necessary, pass such order in relation thereto as it deems fit. The decision of the Central Government shall be final and binding.

(8) The shelf life or date of expiry of an Ayurvedic medicine defined under clause (a) of section 3 of the Act shall, unless otherwise determined on the basis of scientific data, be as follows (Table 2).

Table 2: *Showing the Shelf life of Different Ayurvedic Dosage forms as mentioned in Rule No. 161 B the D & C Act*

S. No.	Name of the Group of Ayurvedic Medicine	Shelf life as of Ayurvedic medicines	
		as per pre-revised Rule 161-B vide G.S.R. 764 (E) [a]	as per revised Rule 161-B; vide G.S.R. No. 789 (E) [b]
1.	Churna, Kwatha Churna	2 years	2 years
2.	Gutika (Vati-Gutti, Pills, Tablets except Gutika with Rasa)	3 years	(explained in S. No. 37)
3.	Gutika Tablet containing Kasth aushadhi,	3 years	
4.	Gutika, Tablet containing Kasth aushadi and Rasa, Uprasa, Metallic Bhasmas, and Guggulu.	5 years	
5.	Rasaushadhies	No expiry date[1]	(explained in S. No. 38)
6.	Asava-Arista	No expiry date[1]	10 years
7.	Avaleha	3 years	3 year (Includes Khanda, Paka, Guda also)
8.	Guggulu	5 years	5 years
9.	Mandura - Lauha	10 years	10 years
10.	Ghrita	2 years	2 years
11.	Taila	3 years	3 years
12.	Arka	1 year	1 year
13.	Dravaka, Lavana, Ksara	5 years	5 years
14.	Lepa Churna	3 years	2 years
15.	Dant Manjan Powder	2 years	2 years
16.	Dant Manjan Paste	2 years	-
17.	Lepa Guti	3 years	(explained in S. No. 37)
18.	Lepa Malahar (Ointment)/Liniment/ Gels/lotions /creams	3 years	Malahar - 3 years
19.	Varti	2 years (one time use)	2 years
20.	Ghana Vati	3 years	(explained in S. No. 37)
21.	Kupipakva Rasayan	No expiry date[1]	10 years
22.	Parpati	No expiry date[1]	10 years
23.	Sveta parpati	2 years	2 years
24.	Pisti and Bhasma	No expiry date[1]	Pishti and Bhasma except Naga, Vanga and Tamra Bhasma – 10 years

25.	Svarna, Rajata, Lauha, Mandura, Abhraka bhasma, Godanti, Shankha Bhasma, etc.	No expiry date[1]	(explained in S. No. 24)
26.	Naga Bhasma, Vanga Bhasma, Tamra Bhasma[2]	5 years[2]	5 years
27.	Capsules made of soft gelatin (depending upon the content material) for Kashtha aushadhi	3 years	-
28.	Capsules of hard gelatin (depending upon the content material) -containing Kasth aushdhi with Rasa, Bhasma, Parad-Gandhak	5 years[2]	-
29.	Syrup/liquid oral	3 years	-
30.	(Karna/Nasa Bindu) Ear/Nasal drops	2 years	2 years
31.	Eye drops	1 year	1 year
32.	Khand/Granule/Pak	3 years	(explained in S. No. 7)
33.	Dhoopans-Inhalers	2 years	2 year
34.	Pravahi Kwatha (with preservatives)	3 years	Pravahi Kwatha- 3 years
35.	Anjana	-	
	a) Anjana made from Kasthaushadhi		1 year
	b) Anjana made from Kasthaushadhi along with Rasa/Uprasa/Bhasma		2 year
	c) Anjana made only from Rasa/Uprasa/Bhasma		3 year
36.	Sharkar / Panak/Sharbat		3 year
37.	Gutika/Vati	-	
	(I) Gutika or Vati containing Kasthaushadhi along with Rasa / Uprasa / Bhasma/ Guggulu (including Lepa Gutika and Ghan Vati)		5 years
	(II) Gutika or Vati containing only Kasthaushadhi (including Lepa Gutika and Ghan Vati)		3 years
	(III) Gutika / Vati containing only Ras /Uprasa /Bhasma except Naga, Vanga and Tamra Bhasma		10 years
38.	Rasayoga	-	
	(I) Rasayoga containing only Rasa / Uprasa / Bhasma except Naga, Vanga and Tamra Bhasma		10 years
	(II) Rasayoga containing Rasa / Uprasa/ Bhasma along with Kasthaushadhi/Guggulu		5 years
39.	Sattva (derived from medicinal plant)	-	2 years

[a] Anonymous, 2009, The Gazette of India, Extraordinary Part-II, Section 3
[b] Anonymous, 2016, The Gazette of India, Extraordinary Part-II, Section 3

Note 1. Item at Sr. No. 5, 6, 21, 22, 24, 25 have very long shelf life and they became more efficacious with the passage of time and period of ten years shall be mandatory for keeping the records of such items.

Note 2. Bhasmas at Sr. No. 26, start solidifying after five years and they need one or two Puta again before using in the dosage form.

4. Estimation of Shelf Life of Ayurvedic Dosage Forms

It was constantly demand from the manufacturers of Ayurvedic medicines that which guidelines should be adopted for the assessment of the shelf life of the Ayurvedic medicines, as it is mandatory that shelf life to be displayed on the label of the Ayurvedic products. Now as specified in the revised Rule No. 161-B of the D & C Act 1940, that the estimation of the scientific data based

shelf life or date of expiry of the ASU medicine, should be based on the Real-time stability studies of medicines in accordance with the guidelines prescribed in the Ayurvedic Pharmacopoeia of India (API), Part-I, Volume-VIII and it is applicable to all ASU medicine. The guideline as described in the API Part I, Vol. VIII, appendix 3.9 covers almost all the aspect of the factors which should be taken into the account for the assessment of shelf life or the date of expiry of an Ayurvedic medicine e.g. general information, scope, approach towards selection of the batch of the medicine for the newly developed and existing marketed products, closure systems, specifications i.e. Analytical parameters (organoleptic, physical and physico-chemical parameters) criteria for the identity, purity and strength of the product under study, testing frequency, storage conditions (temperature, relative humidity, light) maintained under the Stability Chambers used for the Accelerated/ Real time stability studies and evaluation of the shelf life on the basis of the testing results.

4.1. Guidelines for Estimation of Shelf Life as Prescribed in API Part I, Vol. VIII, Appendix 3.9

(Anonymous, 2010, The Ayurvedic Pharmacopoeia of India, Part I, Vol VIII)

4.2. Stability Testing and Shelf Life Determination for New and Existing Ayurvedic Drugs

(This guideline is not limited only to ASU extracts covered under this volume of API. It shall be applicable to all the licensed ASU medicines)

4.3. Scope and Objective

The objective of this guideline is to specify the method of arriving at shelf life by stability testing. The shelf life determined by the process mentioned in this guideline can be used to decide the expiry date, in case a manufacturer wishes to assign a shelf life longer than one specified by the notification G.S.R. 764 (E) dated October 15, 2009 *(now G.S.R. 789(E), dated 12th August, 2016 - as per revised rule 161-B should be considered).*

The guideline can be used for all patented and proprietary Ayurvedic medicines, both new and existing products.

5. General Information on Stability

Information of shelf life (expiry date) is mandatory requirement for all licensed Ayurvedic medicines. The stability depends on various factors like the nature of the product, the ingredients of the products, the packaging material etc. Stability studies are carried out to demonstrate that the medicine will remain suitable for consumption during shelf period when stored under the condition(s) mentioned on the packaging. On the product label, if there is no mention about any specific storage condition, then it is assumed that the product can be stored at room temperature (below 30^{o}C). For a suitable drug substance, retest period is more appropriate than expiry date.

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 variety of environmental factors such as temperature, humidity, and light, to establish a retest period for drug substance or a shelf life for drug products.

Two approaches can be followed to monitor the stability of the product. The first approach is to store the samples of same batch material at standard storage and accelerated storage conditions and test them periodically. Based on the evaluation of the results, the expiry date or shelf life may be determined.

The second approach is to select samples from batches manufactured over a period of last five years spanning six months and evaluate them simultaneously. Based on the result obtained the expiry date

or shelf life may be determined. This approach is applicable for existing products which do not have yet a declared shelf life. This approach has been referred in scientific literature as the “cross sectional approach”.

5.1. Selection of batches

Formal stability studies should be conducted on at least three primary batches. The primary batches should be of the same formulation as proposed for marketing. For new products, the batches should be manufactured to a minimum of pilot scale by the same route as, and using a method of manufacture and procedure that simulates the final process to be used for production batches. Pilot batches which are at least 1/10 of the commercial batch size can be used. The overall quality of the batches of drug placed in formal stability studies should be representative of the quality of the material made on production scale. Where possible, batches of drug product should be manufactured by using different batches of drug substance. Stability to be performed on each individual strength and container size of the product unless bracketing and matrixing is applied.

For cross sectional approach, at least two batches per year to be selected. For example, if stability to be evaluated for four years eight batches should be selected.

5.2. Container and closure system

The stability studies should be conducted on the dosage form packaged in the container and closure system proposed for marketing (including as appropriate, any secondary packaging and container label). If the container is too large for drug substances the stability studies should be conducted in a container and closure system that is the same as or simulates the packaging proposed for storage and distribution.

5.3. Specification

Specification is a list of tests, reference to analytical procedures and proposed acceptance criteria.

Stability study should include testing of those attributes of the drug that are susceptible to change during storage and are likely to influence quality, safety, and/or efficacy. The testing should cover as appropriate, the physical, chemical, biological, and microbiological attributes. Validated stability-indicating analytical procedures should be applied. Whether and to what extent replication should be performed will depend on the results from validation studies.

The physical parameters included in the specification need not be limited to colour, odour, appearance, shape and taste only. The chemical parameters should include colour reaction, *p*H value, weight variation, disintegration time, bulk density, extractive values, estimation of active or marker or category compound by suitable methods and chromatographic profiling. A suitable bioassay may be employed wherever possible.

The limits of acceptance for the products should be those specified in pharmacopoeia. If limits are not available these should be derived from release specification. Shelf life acceptance criteria should be derived from consideration of all available stability information. It may be appropriate to have justifiable differences between the shelf life and release acceptance criteria based on the stability evaluation and the changes observed on storage. Any differences between the release and shelf life acceptance criteria for antimicrobial preservative content should be supported by a validated

correlation of chemical content and preservative effectiveness demonstrated during development of the product in its final formulation (except for preservative concentration) intended for marketing.

5.4. Testing frequency

For long term studies frequency of testing should be sufficient to establish the stability profile of the drug. For drug with proposed shelf life of at least 12 months, the frequency of testing at long term storage condition should normally be every 6 months over first year, and the second year and annually thereafter through the proposed re-test period or shelf life.

At the accelerated storage condition, a minimum of three time points including the initial and final time points *(e.g.* 0, 3 and 6 months) from a 6 month study is recommended.

Reduced designs *i.e.,* matrixing or bracketing, where the testing frequency is reduced or certain factor combinations are not tested at all, can be applied if justified.

5.5. Storage condition

The world can be divided in to four climatic zones I - IV. This guideline address zone IV. The choice of test conditions defined in this guideline is based on an analysis of the effects of climatic conditions in the zone. Recommended storage conditions are

S. No.	Study	Storage condition	Minimum time
1	Accelerated	$40^{o} \pm 2^{o}$ C / 75 % RH ± 5 %	6 months
2	Long term	$30^{o} \pm 2^{o}$ C / 60 % RH ± 5 %	12 months

Other storage conditions are allowable if suitably justified. For products, which are temperature sensitive, to be stored in lower temperature which will then become the condition designated long term storage temperature. The accelerated testing should be then carried out at least 10^{0} C more than the long term storage condition along with appropriate relative humidity condition for that temperature.

The reference samples for the above study should be stored in a temperature less than 10^{o}C.

5.6. Evaluation

The purpose of stability is to establish, based on testing a minimum of at least three batches of the drug, a retest period applicable to all future batches for the drug substance, or a shelf life and label storage instructions applicable for all future batches of the drug product manufactured and packed under similar circumstances.

An Ayurvedic drug can be considered to be stable if “no significant change” occurs during at any time of testing at accelerated storage condition or at real time storage condition.

“Significant change” for a drug is defined as

1) A + or - 20 per cent change from the initial assay value (If the drug is analysed for its marker). A + or - 15 per cent change from the initial assay value (If the drug is analysed for its active compound).

2) Appearance of new spots in Identification by TLC (when compared with the sample stored in less than 10^{o} C) or completely disappearance of existing spot.
3) The physico-chemical parameters (moisture, ash, particle size) shall not vary beyond 25% of the initial value.
4) Failure to meet the acceptance criteria as per individual monographs or specification.
5) Failure to meet acceptance criteria for appearance (Physical attributes, and functionality tests *e.g.,* colour, phase separation, caking, hardness).

6. Conclusion

The scholars of the Ayurveda indicated the *Saviryata Avadhi* (shelf life) of the different dosage forms and also aware that the in the due course of time, pharmaceutical processing, nature of ingredients and by virtue of other factors the *Virya* (Potency) of the Ayurvedic medicine is tend to reduces and within that specified period the medicine is good for therapeutics. In the current scenario, i.e. revised Rule No. 161-B of the D & C Act 1940, specified the shelf life or date of expiry of an Ayurvedic medicine defined under clause (a) of section 3 of the Act unless otherwise determined on the basis of scientific data. While the aforesaid rule, also specify that the guidelines mentioned in the API Part I, Vol. VIII should be followed for the estimation of scientific data based shelf life or date of expiry of the ASU medicines defined under clause (h) of section 3 of the Act (i.e. patent & proprietary ASU medicines) based on the Real-time stability studies. The prescribed guideline in the API, Part I, Vol. VIII, under appendix 3.9 refers guidelines for the assessment of the shelf life pertinent not only for the Ayurvedic medicine but it is equally applicable for Siddha and Unani medicine also. The guideline mentioned in the API, Part I, Vol. VIII, covers general information, scope and modus operandi for estimation of shelf life e.g. approach for selection of the batches, closure system, specifications i.e. Analytical parameters under consideration, testing frequency, maintenance of internal environmental conditions of the Stability Chambers, evaluation and inference of the shelf life on the basis of the testing results. However, there is a wide gap to establish the shelf life of various classical and patent ASU formulations on the basis of the scientific data as most of the formulations are comprising polyherbal/mineral compounds, absence of studies on interactions between the ingredients, unavailability of the information on active markers, natural attributes of the ingredients and formulations, large number of the marketed products and large numbers of smaller manufacturing industries.

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