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Shelf Life Studies Conducted on Ayurvedic Medicines - A Review

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ABSTRACT

Introduction: Although shelf life (SL) of Ayurvedic dosage forms has been mentioned by D & C act and rules, still chances of variability in SL in view of predominant component of raw materials from biological sources cannot be denied. Evaluation of shelf life of individual Ayurvedic formulation (AF) with respect to adopted pharmaceutical (procurement, manufacturing and storage specifications) is needed. Hence review of online published shelf life studies (SLS) of Ayurvedic formulations was carried out. **Aim and Objectives:** To summarize various online published researches on Shelf life evaluation of AFs in view of observed shelf life, frequently tested analytical parameters for dosage forms and to compare agreement between shelf life period of dosage form by classics, current legal recommendations and online documented results of shelf life studies. **Materials and Methods:** SLS of AFs were searched from online published, authentic databases, search engines of research journals and research journals etc. They were evaluated for studied analytical parameters, method of evaluation, shelf life etc. Data thus obtained was arranged and interpreted. **Result and Conclusion:** SLS of total 20 poly herbal AFs (11 Accelerated and 9 real time studies) conducted over duration of 6- 24 months with storage in airtight containers including 8 *Churna*, 3 *Ghrita*, 7 *Avaleha* and modified dosage form of granules and one study of each dosage form of *Rasaushadhi*, and *Arka* were found published. Loss on drying, microbial load, total ash, pH, HPTLC were the mostly used parameters.

KEYWORDS

Ayurvedic formulations, Expiry Date, Saviryatha Avadhi, Shelf life, Stability Study



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INTRODUCTION

Shelf life is comprehensive of time, from the date of manufacture, that a drug product is predicted to stay enclosed by approved product specifications, whereas, embrace on below outlining conditions. The phrase, “shelf life” and “expiry date” is often interchangeably used in the industry, as both terms reflect the same concept as shelf life generally relates to a drug’s quality over a such that definite period, whereas the expiration date relates to both quality and safety of a medication at a specific point in time¹. There is a duration of time wherever a product be able to stable and safe to be used, but is made limited based on thorough stability research. Shelf life/expiry dates replicate the time when a product resolve work both safely and effectively. This is why, “shelf life testing” is correspondingly denoted as “stability testing.” The amount of time a product can maintain its identity, strength, therapeutic effect in a stable condition under certain environmental conditions, equates to its shelf life².

The concept of *Virya* (Potency) of the various *Ayurvedic* dosage forms is 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 is maintained or it is

the time limit by which the drug reduces its original potency up to some extent and should be recommended for prescription before lapse of that specified period As per the citation given in the *Susurutha Samhitha*, a drug whether it is fresh or old, can be utilized for therapeutic purpose up to which its qualities (appearance, taste, smell, etc.) remains in inherent conditions³. Even though the concept of *Saviryta Avadhi* (shelf-life) of *Ayurvedic* dosage forms were included in the initial classics of *Ayurveda* like *Charaka Samhita*, but descriptions given 13th Century AD in texts such as *Vangasena Samhita*, *Sharangadhara Samhita* and *Yogaratanakara*.. The reason behind that may be that the ancient physicians used their medicinal preparations of freshly prepared basic dosage forms *Swarasa* (juice), *Kalka* (paste) etc. were enough to them until medieval period, hence due to plenty of availability of fresh resources and their effectiveness after using within short time and willingness, feasibility of physicians as well as patients to spent time on manufacture of medicine and firm adherences on principle of individualized medicine among many other reasons, *Ayurveda* medicines were not commercialized on industrial level. Though the concepts have a sturdy background; considering the pharmaceutical



development, a need is felt to re-evaluate the age-old concepts, redefine their précised ranges by following current scientifically accepted norms. In current era, due to development and adaptation of packaging and storage technology by Ayurvedic industries, it is needed to re-study and re-establish shelf life of Ayurvedic formulations. In this complexity of modern era, the regulations for shelf life of ASU drugs were needed to be modified. In the current scenario, i.e. revised Rule No. 161-B of the D & C Act 1940, 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 as guideline is to specify the method of arriving at shelf life by stability testing. These guidelines cover 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 *Ayurveda* medicine. In this guidelines details of evaluation of a shelf life study of ASU drugs, 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) to be 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 is mentioned⁴.

While there is average shelf life period mentioned in the API, it is only categorized as *Avaleha*, *Girtha*, *Churna* etc. but the testing shelf life of each and every poly herbal medicine is necessity because stability of the drug may vary under influence of multiple environmental factors like temperature, humidity, light, oxygen, moisture, additional ingredient or excipients within the dosage form, particle size of drug, microbial contamination, trace metal contamination, leaching from the container, etc. Quality of the raw materials used (from the harvesting), combination of the raw material, method of preparation, container used to pack and storage condition etc. Here the effort has been done to collect the published articles or research work carried out on online published shelf life studies of Ayurvedic formulations till the date.

AIMS AND OBJECTIVES

To summarize various online published researches on shelf life evaluation of Ayurvedic formulations in view of



observed shelf life, frequently tested analytical parameters for specific dosage forms and to compare agreement between shelf life period of dosage form by classics, current legal recommendations and online documented results of shelf life studies.

MATERIALS AND METHODS

Search method: In present review, shelf life study of Ayurvedic medicines were compiled from relevant online published research papers in various databases of research journals like J gate, Springer, Scopus, Pub med, Yahoo, Cochrane library, Wikipedia, Worldwidescience.Org, NISCARE online periodicals, Ovid, Web of science

Hindwi Publications, Biomed central, Health system global-HSG, Taylor and Francis, Google, Google India, Google scholar, Wolter coulter and Omics international. Searched for words “shelf life”, “Stability” and “*Saveiryata Avadhi*” prefixes and suffixes with sentences “*Ayurveda, Ayurvedic*”, “Herbal product”, “study”, “study on”, “expiry date of researches on *Ayurveda* product”, “*standardization, Ayurveda*”, *Ayurvedic* dosage form, study period, Packing and storage condition, study duration, type of stability study, parameters used were concerned.

Inclusion criteria: Online published articles of a shelf life or stability study on individual Ayurvedic product were highly concerned.

Exclusion criteria: Herbal products not directly used as Ayurvedic formula, Literature review article, Articles about regulations of ASU drug, single herbal plant (in other than Ayurvedic dosage form), herbal food preparations like pickle and jam and shelf life studies conducted on products of other system of medicines, products of other traditional medicines, allopathic medicines etc. were excluded.

Available research papers were categorized, information was gathered under certain common headings.

OBSERVATIONS

Total studies:

The number of publications of original researches regarding shelf life studies were less and more over there were few research papers have been conducted towards Ayurvedic medicines. Thirteen articles were reviewed here and twenty Ayurvedic formulations have been included within those studies as summarized figure 1.

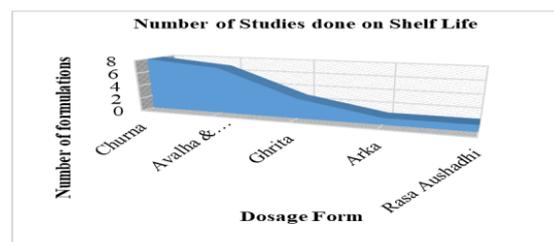


Figure 1 Number of Preparations carried out on studies



Even though above studies were carried out on stability studies, the aims and objectives of the each authors were not the same. Foremost intention was to ensure the period remaining their quality of active compounds in pharmaceutical products and providing evidence based data to establish shelf life period for their Ayurvedic dosage forms, but Saraswathy and others focused mainly on the different storage and packaging conditions⁵, Sunil Kumar at al had given special attention to ensure the capability of using HPTLC as a main parameter of stability testing⁶. Chatterjee at al intended to study radiation processing (gamma/ electron beam) as an effective quality control tool for hygienization and extending shelf life of an herbal formulation⁷. Nidhi Khemuka at al had been published the work done by aiming comparison of a shelf life with *Avaleha* and its granules with same ingredients⁸. As well there was a Comparative study carried out on *Kumkumādi Ghrita* prepared with *Nagakeshara* in addition to *Keshara*⁹ and *Shrisha avaleha* prepared by *Kanji* and water¹⁰ were reviewed.

Study Type:

Accelerated stability study:

As per **Figure 2**, 55% studies followed the method of Accelerated stability study for their medicine.

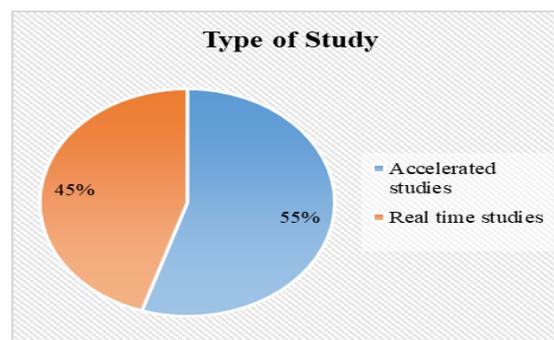


Figure 2 Study Pattern of followed by scholars on Shelf life study

Accelerated stability study and Storage conditions of Accelerated stability study were conducted as per the International Council for Harmonisation of technical requirements for Pharmaceuticals for Human use (ICH) Q1A (R2). Temperature was maintained at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ while relative humidity was maintained at $75\% \pm 5\%$.

The sample was withdrawn from the stability chamber at the intervals of 0, 1, 3, and six months and evaluated for relevant parameters. Based on the analytical values obtained before and after six months of storage, intercept and slope were calculated. Based on these, the acceptable point to extrapolate the accelerated stability data is set as 10% degradation. The mean obtained of these months were multiplied with the real-time aging factor. As India comes under climatic zone III countries, the real-time aging factor becomes 3.33 that was used to extrapolate shelf life. Formula: months when 10% degradation occurs = [0-



month assay value – {(0-month assay value) × 10/100}] – intercept/ slope.

2. Real time stability study:

45% studies were conducted through real time stability method as described Figure 2.

Generally these studies were conducted under normal room temperature and normal humidity conditions. As the normal temperature and humidity is depending according to the environmental condition of the place, two studies were conducted under room temperature of (RT) 25 °C ± 2 and relative humidity (RH) 60% ± 5, one study was under RT = 30°C ± 2°C, 60%RH ± 5%. In one study was adopted broad range of temperature and humidity like RT = 25 - 32°C and RH = 50–85 %, while other some studies did not mentioned exact temperature and humidity, whereas generally ICH guidelines from Q1 to Q11 were found to be followed.

Majority of the real time studies were continued until six months and maximum time period was until 24 month otherwise some studies were carried out until disintegration took place before completion of the planned period.

Packing conditions:

Different containers were used to fulfill different aims in around 90% studies air tight food grade plastic containers were used. Remaining 10% utilized air tight food

grade plastic containers having aluminum foil covering, transparent plastic bottles with transparent screw cap, sterilized glass bottles or sterile glass containers, colorless and amber colored glass bottles, polythene jar, colorless glass bottle exposed to light, colorless glass bottle kept in dark, glass bottle exposed to light, airtight glass containers. Mostly reserved to 50 -100 g of sample in each container.

Evaluation of Shelf life of different formulations: Upon comparison of shelf life studies, about all the 8 *Churna* which were studied, as seen in **Table 1**,

Table 1 Evaluated Shelf life

| | Dosage form | Shelf Life |
|-----------------------------|---|-----------------------|
| Churna | | |
| 1 | <i>Rasayana churna</i> | 2 years 0.9 month |
| 2 | <i>Constac plus powder</i> | 2 years |
| 3 | <i>Hutabhugadi Churna</i> | 11.41 month |
| 4 | <i>Amritameharichurnam</i> | 1 year and 6 month |
| 5 | <i>Hingvatsaka Churna</i> | At least for 6 months |
| 6 | <i>Dasamula Kvatha Churna</i> | 4 month |
| 7 | <i>Hridya Yoga Churna</i> | 3 years and 7 months |
| 8 | <i>Nishamalaki churna</i> | 3 years 7 months. |
| Avaleha and Granules | | |
| 9 | <i>Kamsaharītakī avaleha</i> | 1 year and 6 months |
| 10 | <i>Kamsaharītakī granules</i> | 2 years and 3 months |
| 11 | <i>Shirisha Ashwagandhadi Avaleha</i> (metallic component present) | 8 years and 7 months |
| 12 | <i>Vasavaleha</i> | |
| 13 | <i>Trivrit Avaleha</i> | 1 year and 11 months |
| 14 | <i>Shirishavaleha</i> prepared by Kanji | 2 years |
| 15 | <i>Shirishavaleha</i> prepared by water | 1 years and 4 month |
| Ghrita | | |



| | | |
|----------------------|---|-----------------------|
| 16 | <i>Kumkumādi Ghrita Prepared using Kesara</i> | 1 year and 4 month |
| 17 | <i>Kumkumādi Ghrita Prepared using Nagakesara</i> | 1 year and 4 month |
| 18 | <i>Brahmighirta</i> | At least for 6 months |
| Arka | | |
| 19 | <i>Ajamodarka</i> | 4 th month |
| Rasa Aushadhi | | |
| 20 | <i>Laghu Sutashekhara Rasa</i> | 2 years and 8 months |

evaluated shelf lives are array from broad range of minimum four months to maximize 43 month^{5, 6, 7, 11-14}. Average Shelf life for *Churna* is 21.675 month as the details are discussed in **Figure 3**.

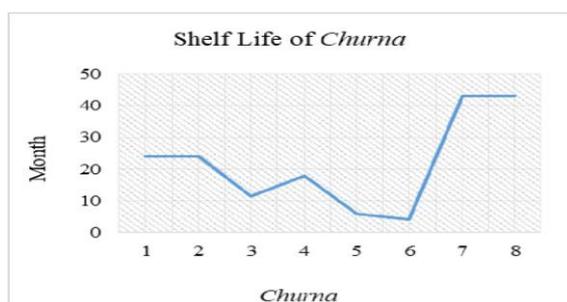


Figure 3 Shelf life range of *Churna*

While comparing *Avaleha* and granules, it has 22 month shelf life with little fluctuation except *Shirisha Ashwagandhadi Avaleha* highlighted shelf life of eight years and seven month¹⁰, as it is an outlier from this data¹⁵⁻¹⁷ as per **figure 4**.

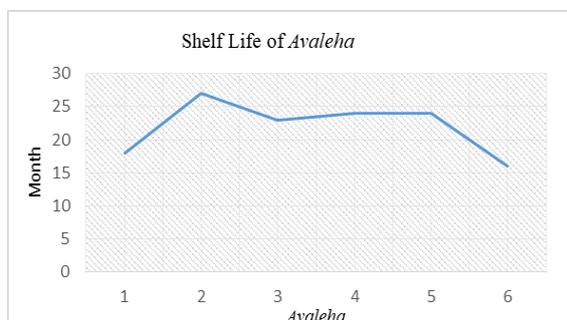


Figure 4 Shelf life range of *Avaleha*

Moreover granules modified from the *Avaleha* exhibit more shelf life

comparatively same product of *Avaleha*⁸. *Shirishavaleha* prepared by *Kanji* media were shown more stability than *Shirishavaleha* prepared by water media⁹. *Ghritha* was evaluated in the range of a shelf life of six months to one year and noted to have four months of maximum shelf life^{5, 9}. Calculated Shelf life of *Laghu Sutashekhara Rasa* is two years and 8 months¹⁸ and *Arka* was started deterioration from four month⁵.

Parameters Used:

Organoleptic Parameters:

All the scholars used organoleptic parameters for evaluation of declination of the product quality. Color, odor and taste are the most popular characteristics additionally touch and consistency are also remarkable.

Physico-Chemical Parameters:

Most of the investigators used selected approximate five parameters to compare the quality of their polyherbal product according to relevancy of their drug and their compatibility. As per the **Figure 5**;

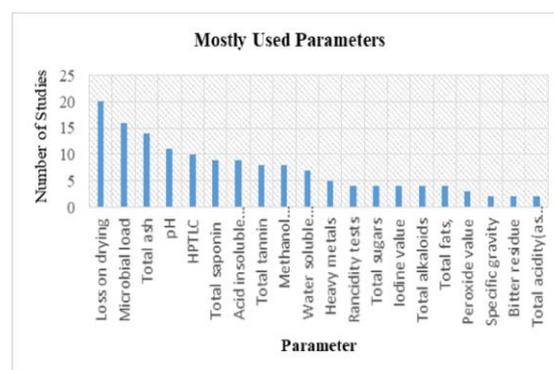


Figure 5 Mostly used parameters for Shelf life study



there were 32 parameters used by 20 scholars and from that 20 parameters used by at least two scholars and 12 parameters each were used by only single study as seen in **Table 2**.

Table 2 Single used Parameters.

| S.No | Specific Parameters |
|------|-------------------------------------|
| 1 | Refractive index |
| 2 | Total fat |
| 3 | Assay for curcumin, and gallic acid |
| 4 | UV spectrum |
| 5 | Residual Drug Content |
| 6 | Bulk and tapped density |
| 7 | Hausner's ratio |
| 8 | Compressibility index |
| 9 | Average weight of tablets |
| 10 | Tablet hardness kg/cm |
| 11 | Tablet hardness kg/cm |
| 12 | Alkalinity |

Mostly twelve parameters out of them were used for evaluate churna formulary as mentioned in **Figure 6**. Loss on drying, microbial load, total ash, pH value, HPTLC, total saponin, Acid insoluble ash, total tannin, methanol soluble extractives, and water soluble extract was among most durable parameters among them.

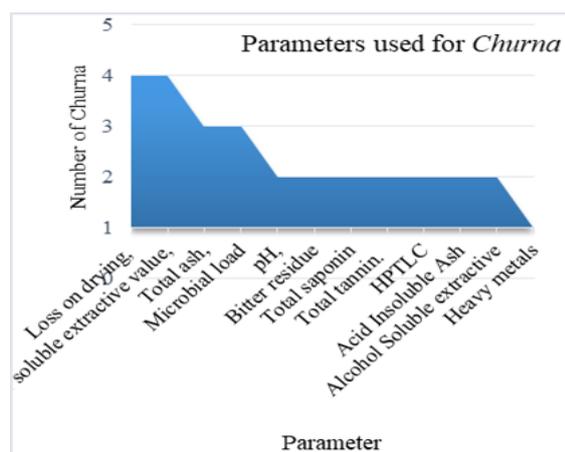


Figure 6 Number of parameters used for churna Total plate count, total Yeast/Mould Count, E.coli, Salmonella, S.aureus and

P.aeruginosa were studied under microbial study and Arsenic, Lead, Mercury and Cadmium studied under Heavy metal content.

RESULTS AND DISCUSSION

Though the most performed stability test method for Ayurvedic drugs are normally suggested to follow real time stability study⁴; 55% of the studies Among 20 studies, had been conducted under the methods of Accelerated shelf life study, and remaining 45% followed real time or long term shelf life study Most of the real time studies were discontinued by the researchers themselves at the end of the six month, Nevertheless long-term study should be continued until the product deteriorated 10 %. This was produced misperception to get the right decisions. Accelerated study is becoming the major role of shelf life study for Ayurvedic sector and it is unavoidable as managing the real time study for long period is incredible to the scholars in present-day.

Packing of the medicine in 50g to 150g food graded plastic, transparent container with screw-cap is feasible to the majority of drug products and to the public also but as per the conditions, packaging material will be changed. Air tight container is essential condition for the long lasting purpose.



Amber colored bottle was comparatively provided more shelf life than light colored and colorless glass bottles. One enquiry was done by Saraswathy et al⁵ about to study of the effectiveness of container however it was slightly exhibited the deviation, and it provided less evidence for effectiveness of container and storage conditions. There might be some another unexpected factor influenced to that study as mentioned by the author himself. In the same research, *Arka* was subjected to study shelf life with different storage conditions, has exhibited no any change during period of 6 months data with different containers. This research inspires scope for further research.

Organoleptic parameters like colour, consistency, odor, taste are the most significant parameters for each drug with classical reference and experience of the relevant people. Loss on drying, total ash, pH value, Acid insoluble ash, methanol soluble extractives, water soluble extractive was the most durable and economical parameters used by most of the scholars. HPTLC, Refractive index, UV spectrum etc. are standard parameters for shelf life evaluation though these parameters are comparatively costly. Ninety percent of studies were carried out on microbial load and Heavy metal content as these are the important parameters not only for shelf life but also for product standardization.

Almost any of the above mentioned organoleptic and physico-chemical parameters can be used to compare the quality of the product, but stability testing of herbal product is rather complicated comparing to chemically defined substances because the active substances in herbal products are not individually present and mostly they are in complex manner. Also it is difficult to define Ayurvedic pharmacological attributes of formulation or a drug like *Virya* etc. with modern parameters. As well *Ayurvedic* polyherbal products are mostly combined formulations of two or more herbs with similar constituents which leads to more analytical challenges. Herbal substances may be thermo stable or labile, volatile, or unstable which hamper the physico-chemical testing. Modern analytical techniques like high performance liquid chromatography (HPLC) or gas chromatography (GC) and thin layer chromatography (TLC) methods, quantitative determinations by UV Visible NIR, IR (far, near) spectroscopy or hyphenations of these with LC and GC mass coupling is well-intentioned as analytical parameters but, they are highly sophisticated and expensive methods. Even though using of these tools and preparing acceptable data base is essential in this era to overcome the international challenges¹⁹. The research concerning radiation process



used for the hyginization purpose is a considerable technique for value addition processing of Ayurvedic drugs, provided that it is evaluated for safety and efficacy. Average Shelf life of *Churna* in present studies has been shown nearer to two years which it is compatible with the gazette notification now G.S.R. 789(E), dated 12th August, 2016 above mentioned⁴. There is wide range of fluctuation in observed shelf life which denotes that, stability of *churna* depends on multiple factors or controlling reasons which affects its hindrance for maintenance of shelf life. Mostly two *Churna* forms have shown improved stability considerably and when these studies were reviewed, it was observed that, one of them added permitted preservatives and excipients and another was keen about the hygienic status of proceeding. Method of procedures is highly sensitive to affect shelf life of *Churna* form than other medicines. Rani et al used following procedures for their preparation and has shown good shelf life, hence it provides important message to the manufactures²⁰. They were purchased raw material in the fresh form, rinsed with running tap water and shade dried as described by Ayurvedic formulary of India. Then again dried in hot air oven at 60°C for two hours. All plant material was stored in airtight glass containers. All ingredients

were powdered separately in the electric grinder and sieved through no. 80 mesh. These powdered ingredients were weighed separately in the ratio mentioned in NFUM and mixed rigorously in an electric kitchen mixer to get homogenous powder. Also in packing stage researcher stated that they followed the precautions while packaging. This research gives significance of following GMP from the beginning to end of the product is better way to increase shelf life as well as quality of the product. Besides that, above articles turns the mind back for thinking innovatively as per shelf life study of *Dashamoola Kvatha Churna*, the product was extremely affected within four months in airtight container at the normal storage condition⁵ governs that not only the good manufacturing procedures but also the necessity of good harvesting practice and good cultivating practice. Studies of *Avaleha* exhibited average two years of shelf life period in between classical reference and current scenario⁴. *Kanji* contributed more stability for *Avaleha* than water media which used for preparation of *Avaleha*¹⁵ metallic compounds increased shelf life supremely as shown in *Shirisha Ashwagandhadi Avaleha*¹⁰. Two types of one *Grita* preparation study⁹ has shown compatible *Saveeryata Avadhi* of *Grita* with classical reference.



Though long-term stability is suggested for Ayurveda preparations, an accelerated study is also practicable. Selected reliable six parameters are most enough with organoleptic characteristics which are mostly used for shelf life evaluation of stated dosage forms. Shelf life study for each Ayurvedic product is important as stability is dependent over multiple factors. Controlling the issues as much as possible is significant strategy for enhancement of the stability and it improves the quality and standard of Ayurvedic product which give high validation for Ayurveda.

CONCLUSION

Shelf life studies of total 20 classical Ayurvedic formulations [5 classical dosage forms;

Churna (8), *Avaleha* (6), *Ghrita* (3), *Arka* (1), *Rasaushadhi* (1) and modified dosage form Granules (1)] were found published online. Maximum studies (19) were aimed at physicochemical stability and one aimed at microbial stability. Total 30 parameters were used in these studies with only HPTLC as sophisticated instrumental analysis with lack of quantitative evaluation of individual, phytochemical markers. Not only implementation of the good manufacturing practice, but adoption of good cultivating practice, good harvesting

practices, adoption of recommended processing guidelines (post-harvest management), and good storage practices are also effective factors. Following standard hygienic procedures, use of modern technologies, introducing standard containers, dosage modifications, combination with metallic ingredients or formulations and preservatives, considering on storage condition so as to overcome environmental factors will enhance the shelf life of Ayurvedic products.

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