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RESEARCH ARTICLE

Concept of Stability Study of *Churna Kalpana*

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ABSTRACT

A common myth exists among people that *Ayurvedic* medicines do not have an expiry date, but it is not true. Concept behind expiry means that after a certain period, the substance that is used as medicine undergoes changes, which make it ineffective. That period is known as expiry date or shelf life in modern system of medicine. This concept was described in 14th century by Acharya Sharangdhar as *Saviryata Awadhi* in his textbook *Sharangdhar Samhita.* Recent development in the field of *Ayurvedic* pharma industries has reestablished old principles through evidences. Among the description of all five primary dosage forms, *Churna* (powder) has been considered in this study. There are numerous factors that affect its shelf life, which have been discussed in this study. Based on that, we conclude that by improving storage conditions, adding additives and preservatives, degradation of *Churna* can be checked.

Keywords: *Churna*, Shelf life, Stability.

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INTRODUCTION

Ayurveda is the oldest system of medicine, which is mainly concerned with keeping the body fit, and its main objectives are preventing as well as curing the disease.[1] Therefore, there is a need for constant research on the therapeutic agents that keep the body fit, increase its capacity to fight against a disease, and bring it back to normal. These therapeutic agents are termed as drugs. The success of a physician lies in identifying the disease in the most appropriate way and prescribing the most effective drug accordingly. For this purpose, herbs, minerals, and metals are used. All these drugs need some kind of processing to enable them to be suitable for internal use and more effective in therapeutics. This can be achieved with the help of basic "*Panchvidha Kashaya Kalpana,*" i.e., *Swarasa, Kalka, Kwatha, Hima,* and *Phanta*.[2] *Panchvidha Kashaya Kalpana* denotes the fundamental operations involved in the modification process of a drug. These preparations are quiet effective, but there is a problem that all these are worthless within a little time, which raised a question among our ancient sage, i.e., shelf life.

To keep these things in mind, Acharya Sharangdhar first mentioned about *Saviryata Avadhi*[3] of various formulations that is known as shelf life or expiry date or stability in the modern system of medicine. *Saviryata Avadhi* of a formulation depends upon three things, i.e., ingredients, preparation, and form. However, in the beginning, it was ignored due to developmental stage of pharmaceutics, utilization of drug instantly, lack of mass production, and unavailability of equipment.

In the past few decades, the scenario in the pharmaceutical sector has tremendously changed. Along with product safety, efficacy and ethical issues have taken root, traceries in stability testing have also increased, making it an interdisciplinary science where in addition to analytical criteria, pharmaceutical, technological, biochemical, and biotechnological criteria have become important. This is the basic reason behind this review work, to collect information about the factors responsible for affecting *Saviryata Avadhi* of *Churna* (powder).

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MATERIALS AND METHODS

The present study aimed to collect relevant literature from various sources, including ancient textbooks along with recent research evidences in the context of shelf life.

Ayurvedic Concept of *Saviryata Avadhi* (Shelf Life)

Ayurveda has its roots in *Veda*, which is one of the oldest literatures available on earth. Therefore, from the period of *Veda* to modern era, there is a continuous development in the context of various dosage forms and formulations. For convenience, this can be divided into four periods:

1. *Vedic Kala:* The drug dosage forms (*Bhesaja*) and physician (*Bhisaka*) are mentioned in *Veda* but *Chikitsa Grantha* (pharmaceutical aspects) are not described in detail.

2. *Samhita Kala:* The fundamental books on *Ayurveda* are *Charaka Samhita* and *Sushruta Samhita.* Acharya Sushruta explored various aspects regarding soil that should be used for the drugs of different therapeutics properties.[4] He has also mentioned about *Bhaisajagar* (drug store room).
3. *Samgraha Kala:* This period includes chiefly *Astanga Sangraha* and *Astanga Hridya*, but during this period, most of the information of Acharya Charaka and Acharya Sushruta was followed by other ancient scientists with a little change.[5]
4. *Adhunika Kala:* Acharya Sharangdhar explained "*Saviryata Avadhi"* as the period during which the drugs contain its *Veerya* or potency. He has also specified the use of raw drugs for the preparation of various formulations in the context of its stability.[3] Today's developed pharmaceutical branches are the result of his incessant and meticulous effort.

Concept of *Veerya*

Veerya, *shakhti*, or potency of a drug is most active principle among *rasa, guna, vipaka, and prabhava*. Acharya Charaka explained that *Veerya* of any drug is responsible for its pharmacological actions. Therefore, *Saviryata Avadhi* is defined as the maximum period during which the drug contains its *Veerya* (potency).

Modern Aspect of Shelf life

Stability of a pharmaceutical product may be defined as the capacity of a particular formulation, in a specific container/closure system, to remain within its physical, chemical, microbiological, therapeutic, and toxicological specifications. Assurances that the packaged product will be stable for its anticipated shelf life must come from an accumulation of valid data on the drug in its commercial package. These stability data involve selected parameters that taken together form the stability profile. Pharmaceutical products are expected to meet their specifications for identity, purity, quality, and strength throughout their defined storage period at a specific storage condition.[6]

The United States Pharmacopeia defines the stability of a pharmaceutical product as an "extent to which a product retains, within specified limits, throughout its period of storage and use (i.e. its shelf life) and the properties and characteristics should be the same as it possessed at the time of its manufacture." There are five types of stability that must be considered for each drug (Table 1).

Stability of a drug can also be defined as the time from the date of manufacture and packaging of the formulation until its chemical or biological activities not less than a predetermined level of potency and its physical characteristics have not changed appreciably or deleteriously. Although there are exceptions, 90% of labeled potency generally is recognized as the minimum acceptable potency level.[6]

Table 1: Types of stability[6]

Types of stability	*Conditions maintained throughout the shelf life of drug product*
Physical	The original physical properties, including appearance palatability, uniformity, dissolution, and suspendability, are retained
Chemical	Each active ingredient retains its chemical integrity and labeled potency, within the specified limits
Microbiological	Sterility or resistance to microbial growth is retained according to the specified requirements. Antimicrobial agents that are present should retain effectiveness within the specified limits
Therapeutic	The therapeutic effect remains unchanged
Toxicological	No significant increase in toxicity occurs

Expiry date is defined as the time in which a drug product in a specific packaging configuration will remain stable when stored as per recommended conditions.

"Best before" indicates the date for which the supplier intended the drug should be consumed.

TYPES OF STABILITY TESTING

- *Accelerated Testing*: Studies designed to increase the rate of chemical degradation or physical change of an active drug substance or drug product by using exaggerated storage conditions as part of the formal definitive storage program.
- *Long-term or Real-time Testing*: Stability evaluation of the physical, chemical, biological, and microbiological characteristics of a drug product and a drug substance, covering the expected duration of shelf life and retest period, which are claimed in the submission and will appear on the labeling.
- *Intermediate Testing*: Studies conducted at 30°C/65% relative humidity (RH) and designed to moderately increase the rate of chemical degradation or physical changes for a drug substance or drug product intended to be stored for long term at 25°C.
- *Forced Degradation Testing*: Those studies undertaken to degrade the sample deliberately.
- *Stress Testing*: Stress testing of the drug substance can help to identify the likely degradation products, which can in turn help to establish the degradation pathways and the intrinsic stability of the molecule and validate the stability-indicating power of the analytical procedures used.

In India, critical parameters, used to evaluate stability of *Churna,* are guided by the International Council on

Table 2: Challenging condition for storage of packs for study

Study type	*Temperature*	*Humidity*	*Evaluation time*
Real	25°C ± 2°C	65% ± 5% RH	0, 3, 6, 12, 24, 36 months stations
Accelerated	40°C ± 2°C	75% + 5% RH	0, 1, 2, 3, 6 months stations

Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (Table 2).

CONCEPT OF SHELF LIFE WITH SPECIAL REFERENCE TO *CHURNA* (POWDER)

According to Acharya Sharangdhar, *Churna* retains its potency for 2 months and then gradually starts depreciating.

According to drug and cosmetic (amendment) rule 2005, the official gazette of India notified shelf life of *Churna* as 1 year, but recent amendments of August 2016 show its shelf life is 2 years, while Ayurvedic Formulary of India (AFI) has also mentioned as 1 year (Table 3).

Ayurvedic formulations by nature are not based on single active chemical compound, and hence, any evaluation and discussion regarding their shelf life can be compared with food products. In such formulation, it is extremely difficult to decide an expiry date. Therefore, in such cases, it is preferable and possible to evaluate the "Best before Use" date. This is the date after which one or more properties of any drug or drug substances have shown considerable changes, which can be seen or perceived by consumer or patient and lead to doubts about the quality of the product and efficiency. However, recent advancement of modern technology makes it possible to control and regulate various aspects of processing during production of *Churna* to minimize or eliminate factors that affect shelf life.

FACTORS AFFECTING STABILITY OF *CHURNA* (POWDER)

The following factors have direct effect on the shelf life of formulations:

Physical Factors

- *Temperature:* The rates of most chemical reactions increase with rise in temperature. The observed variation of reaction rate with temperature is an important aspect of the collision theory of chemical reaction. According to this theory, a chemical reaction only takes place when molecules collide. The thermal energy of the colliding molecules converts into energy that is necessary to break chemical bonds and enables the reaction to take place. However, the number of molecular collisions greatly exceeds the number of molecules reacting per second. It has been postulated that reaction only occurs upon collision of molecules possessing a certain minimum amount of energy. As the temperature of the system rises, the proportion of molecules having this minimum energy increases. It follows that at a higher temperature, a greater number of collisions will result in reaction of the molecules and this gives rise to the observed greater rate of reaction.
- *Moisture:* Moisture absorbed on the surface of a solid drug will often increase the rate of decomposition if it is susceptible to hydrolysis, e.g., *Hingwastaka Churna* absorbs moisture from environment because of salt as an ingredient. This is sufficient to activate enzymatic activity and helps to decompose the powder.
- *Light*: Photolytic degradation can be an important limiting factor in the stability of drug. A drug can affect chemically by radiation of a particular wavelength only if it absorbs radiation at that wavelength and the energy exceeds a threshold. Ultraviolet radiation, which has a high energy level, is also the cause of many degradation reactions. The intensity and wavelength of light and the size, shape, composition, and color of the containers may affect the velocity of reaction.

Table 3: Shelf life of *Churna* (powder) according to various sources

Classics text	*Shelf life*
Sharangdhar Samhita[3]	2 months
AFI[7]	1 year
Official Gazette of India[8]	2 year

Chemical Factors

The common causes of chemical instability in pharmaceutical materials involve hydrolysis, oxidation, and reduction.[6,9]

- *Hydrolysis:* This is particularly important in systems containing water, e.g., solutions, suspensions, and emulsions. It is also important in the deterioration of ingredients contained in solid dosage forms, since water may enter as vapors from the atmosphere or as water of crystallization in other ingredients. Solanaceous alkaloid that contains ester linkages is susceptible to hydrolysis. It is usually assumed that if hydrolysis of the alkaloids occurs in aqueous solution, then it is likely to occur in the crude drug if the moisture content increases.
- *Oxidation and Reduction:* Oxidation and reduction involve the loss and gain of electrons respectively. Many oxidation reactions result from the presence of atmospheric oxygen but the required loss of electrons may sometimes occur even when oxygen is absent, e.g., in reactions between oxidizing and reducing agents. However, the decomposition of medicinal compounds usually involves molecular oxygen, such oxidations are termed as autoxidations because they occur spontaneously under normal conditions and often involve free radicals.[10] Crude drugs have less

mass as well as minimum molecular exposure, which reduces autoxidation, but in case of *Churna* (powder form) this process becomes reverse, resulting in more autoxidation that will decompose at a faster rate.

Biological Factors

Exposure to microbes: *Churna* is prepared from herbo-mineral compounds, which is why they have their active principle in the form of phytochemical that helps to increase microbial activity for releasing of microbial enzyme (free radicals) and resulting degradation.

Other Factors

Undesirable reactions between two or more drugs are said to result in a physical, chemical, and therapeutic incompatibility. Physical incompatibility has been defined as a physical or chemical interaction between two or more ingredients, which leads to a visibly recognizable change. Chemical incompatibility is known as a reaction in which a visible change is not observed, while therapeutic incompatibility is defined as undesirable pharmacological interaction between two or more ingredients.

IMPORTANCE OF EVALUATING PARAMETERS FOR *CHURNA*

Physical Parameters

- *Organoleptic characters*: It includes color, odor, texture, and taste.
- *Moisture content*: It affects the particles of hygroscopic materials that lead to aggregation. Sometimes changes in color and odor are observed.
- *Particle size*: The properties of powder can be influenced by the size of the particle or indirectly by the surface area of the powder. As the particle size decreases, the surface area of the particle increases and vice versa.
- *Flowability*: The majority of powders are not free flowing as liquid unless specifically treated to make them. The following reasons may be responsible for poor flow properties of Churna or powders:
  - For cohesion of powders, there is requirement of force known as surface force. Surface forces consist of van der Waals and electrostatic forces that are mainly responsible.
  - Because of irregular shape, particles may interlock bridging and arching.
  - If the particle surfaces are rough, an interparticular friction exists, which affects the cohesion and thus flow of powders.

By increasing the average particle size, making powder in the form of spherical particles and admixtures of additives are some of the methods to improve the flow properties of powder.

Chemical Parameters

- *Extracted values (in selective solvents), volatile matter content*: Water, alcohol, and mixture of these two liquids are the most commonly used solvents for extracting drugs.
- *Total ash*: Ash percentage is an inherent quality of a crude drug and an indication of its purity also.
- *Acid-insoluble ash*: It directly denotes impurity and should be minimum.
- *Thin-layer chromatography/High-performance liquid chromatography (HPLC)*: By the use of HPLC, very small amounts of degradation can be detected.

Microbiological Parameters

- *Total viable count*: It gives a quantitative idea about the presence of microorganisms. The count represents the number of colony-forming units per gram or per milliliter of the sample.
- *Yeast and mold count*: This method is applicable to the enumeration of yeast and mold in powder and powder drug ingredients.
- *Coliform count and other pathogens*: Test of water contamination in which the number of colonies of coliform bacteria *Escherichia coli* per 100 mL of water is counted and the result is expressed as coliform microbial density and indicates the extent of fecal matter present in it.

All the parameters are evaluated for accelerated and real-time studies at definite month's duration (Table 4).

Table 4: Parameters for stability of *Churna kalpana*[11]

Parameters for Churna
Physical parameters
Organoleptic character
Loss on drying at 105°C/Moisture content
Flow ability (depending on the type of drug)
Particle size
Bulk density
Tap density
Chemical parameters
Extractive values
Water-soluble extract
Alcohol-soluble extract
Ash values
Total – ash
Acid-insoluble ash
Water-soluble ash
pH
Volatile matter (if applicable as per the drug)
Assay of constituents (quantity of markers/major active compounds depending upon constituents present in the drug)
Microbiological parameters
Total viable aerobic count
Total Enterobacteriaceae
Total fungal count
E. coli
Salmonella spp.
Staphylococcus aureus
Pseudomonas aeruginosa
Aflatoxins (B1, B2, G1, G2)

CONCLUSION

Suitable methods of storage can check decomposition of *Churna* by oxidation. These include storage in light-protected closed container, oxygen-free packaging, or under inert gas and storage under low temperatures. Such methods are not always practicable, and therefore, it is necessary to use additives like antioxidants and preservatives to control or diminish oxidation process. By that, we can prolong the shelf life of *Churna* and thus we can maintain its stability.

REFERENCES

1. Shastri RD. Charaka Samhita of Agnivesha elaborated Vidyotini hindi commentary. Part Ist, Sutrasthan. Chapter 30. Verse-26. reprint ed. Varanasi, India: Chaukhambha Bharti Academy; 2008. p. 587.
2. Shastri RD. Charaka Samhita of Agnivesha elaborated Vidyotini hindi commentary. Part Ist, Sutrasthan. Chapter 4. Verse-1. reprint ed. Varanasi, India: Chaukhambha Bharti Academy; 2008. p. 67.
3. Vidyasagar SP. Sharangdhara Samhita of Sri Sharangadhara-carya with commentaries Adhamalla's Dipika and Kashi-ram's Gudarthdipika, Poorvakhanda. Chapter 1. Verse-51-53. (1st ed. Varanasi, India: Chaukhambha Surbharati Prakashan; 2006. p. 13-14.
4. Shastri AD. Sushruta Samhita of Maharishi Susruta elaborated Ayurveda Tattva Sandipika hindi commentary. Part Ist, Sutrasthan. Chapter 37. Verse-15-18. 12th ed. Varanasi, India: Chaukhamba Sanskrit Sansthana; 2001. p. 141.
5. Reddy CRK. Bhaisjhya Kalpana Vijnanam. reprint ed. Varanasi, India: Chaukhambha Sanskrita Bhawan; 2005. p. 38.
6. Remington. The science and practice of pharmacy. 21st ed. vol. I. New Delhi: Wolters Kluwer Health (India) Pvt. Ltd; 2005. p. 1025-1029.
7. Anonymous. The Ayurvedic formulary of India. Part Ist. 2nd rev. ed. New Delhi: Department of Indian System of Medicine and Homeopathy, Govt. of India, India; 2003. p. 103.
8. Anonymous. Drugs and cosmetic rules, official gazette of India. Drugs and Cosmetic (Amendments) Rules, New Delhi: Ministry of Health and Family Welfare, Notification; 2016.
9. Carter SJ. Cooper and Gunn's tutorial pharmacy. 6th ed. Delhi: CBS Publishers and Distributors; 2005. p. 98-99.
10. Gupta A, Jaiswal M, Prajapati P. Shelf life of Ayurvedic dosage forms – traditional view, current status and prospective need. IJTK 2011 Oct;10(4):672-677.
11. Lohar DR. Protocol for testing Ayurvedic, Siddha and Unani Medicines. Ghaziabad: Department of AYUSH, Ministry of Health and family welfare, Pharmacopoeial Laboratory for Indian Medicine, Government of India; 2007. p. 21.

हिन्दी सारांश

चूर्ण कल्पना की सवीर्यता अवधि की संकल्पना

नीतू[1], हरीश के. सिंघल[2], खेमचन्द शर्मा[3]

लोगों में एक सामान्य भ्रम है कि आयुर्वेदिक औषधियों की समाप्ति तिथि नहीं होती है परंतु यह सही नहीं है। समाप्ति की संकल्पना है कि वह समय जिसमें कोई द्रव्य जो औषध के रुप में प्रयोग किया जाता हो, में परिवर्तन होकर प्रभावहीन हो जाता है। उस समय को आधुनिक विज्ञान में समाप्ति तिथि या निधानी आयु कहते हैं। इस संकल्पना का सर्वप्रथम वर्णन आचार्य शार्ङ्गधर ने 14वीं शती में शार्ङ्गधर संहिता में सवीर्यता अवधि के नाम से किया था। आयुर्वेदिक फार्मा के क्षेत्र में हो रहे नवीन विकास में पुरातन सिद्धांतों को तथ्यों द्वारा पुनः स्थापित किया जा रहा है। इस लेख में मौलिक पंचविध कषाय कल्पनाओं में से चूर्ण कल्पना पर विचार किया गया है। चूर्ण की सवीर्यता अवधि को प्रभावित करने वाले अनेक कारकों का वर्णन इस लेख में किया गया है, जिनके आधार पर निष्कर्ष निकलता है कि भण्डारण स्थिति एवं सम्यक् संरक्षक द्रव्यों का उपयोग कर चूर्ण के विघटन को रोका जा सकता है।