RESEARCH ARTICLE

Concept of Stability Study of Churna Kalpana

1Neetu, 2Harish K Singhal, 3Khem Chand Sharma

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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Conflict of interest: None

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. Therefore, there is a need for constant research on the therapeutic agents that keep the body fit, increase its effectiveness 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 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).

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. He has also mentioned about Bhaisajyagran (drug store room).

3. Samgraha Kala: This period includes chiefly Astanga Sangraha and Astanga Hridaya, but during this period, most of the information of Acharya Charaka and Acharya Sushruta was followed by other ancient scientists with a little change.

4. Adhunika Kala: Acharya Sharangdhar explained “Saviryata Avadhi” as the period during which the drugs contain their Veerya or potency. He has also specified the use of raw drugs for the preparation of various formulations in the context of its stability. 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, gupta, 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.

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.

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...
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.

**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

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**Table 2:** Challenging condition for storage of packs for study

<table>
<thead>
<tr>
<th>Study type</th>
<th>Temperature</th>
<th>Humidity</th>
<th>Evaluation time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>25°C ± 2°C</td>
<td>65% ± 5% RH</td>
<td>0, 3, 6, 12, 24, 36 months stations</td>
</tr>
<tr>
<td>Accelerated</td>
<td>40°C ± 2°C</td>
<td>75% ± 5% RH</td>
<td>0, 1, 2, 3, 6 months stations</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Classics text</th>
<th>Shelf life</th>
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</thead>
<tbody>
<tr>
<td>Sharangdhar Samhita</td>
<td>2 months</td>
</tr>
<tr>
<td>AFI7</td>
<td>1 year</td>
</tr>
<tr>
<td>Official Gazette of India8</td>
<td>2 year</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Parameters for stability of Churna kalpana</th>
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<tr>
<td><strong>Table 4</strong></td>
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**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

हिन्दी सारांश

चूर्ण कल्पना की स्वीकृति अथवा की संरक्षण

नीदूँ, हरीश के., सिंहले, खेलचंद शार्मा

लोगों में एक सामान्य ब्रम्ह है कि आयुर्विदिक उद्बोधनों की समाधि नहीं होती है परंतु यह सारा नहीं है। समाधि की संरक्षण है कि वह समय जिसमें कोई इथर जो आंतर के रूप में प्रयोग किया जाता है, में परिवर्तन होकर प्रभावशील हो जाता है। उस समय की आयुर्विदिक विज्ञान में समाधि विधि या निभानी आयु कहते हैं। इस संरक्षण का सर्वोच्च वर्ण आयुर्विदिक शारीरिक कार्य शारीरिक व शारीरिक सहिता में स्वीकृति अथवा की के नाम से किया था। आयुर्विदिक वर्ण से क्षेत्र में हो रहे नवीन विकास में पुलिस रिपोर्टें की तथ्यों द्वारा पुनः न्यायित किया जा रहा है। इस लेख में नयी समस्त कार्य कल्पनाएं में से चूर्ण कल्पना पर विचार किया गया है। चूर्ण की स्वीकृति अथवा की का प्रयोग करने वाले अनेक कारकों का वर्णन इस लेख में किया गया है, जिसके आधार पर निष्कर्ष निकालता है कि भगवान्त रिपोर्ट एवं सम्प्रभु संस्करण अवस्था का उपयोग कर पूर्ण के विधान को रोका जा सकता है।