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A review on stability studies and standardization of ayurvedic dosage forms-prospective need

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Abstract

There is a very few Ayurvedic classical books that's having the concept of shelf life or stability data. *Charaka, Sushruta* etc. also doesn't have an indication of shelf life data. The importance of quality parameters, the duration of use, storage condition etc of the Ayurvedic formulations are mentioned in some Ayurvedic text like Vangasena, Yogaratnakar etc. Now a days due to increase numbers manufacturers, to meet the demand of the customers the manufactures are using different packaging materials for different finished dose formulations. The stability data of all these formulations plays an important role in terms of efficacy of the ingredients the formulation is having. Government of India also has issued Gazette notifications with some amendments of their earlier notifications for the shelf life of different Ayurvedic dosage forms. As per the Drugs and Cosmetic Act 1940, the Ayurvedic industries need to submit the shelf life studies of the respective formulations to the regulatory body. Hence there must have standard scientific data of shelf life for different geographical region. Different technologies are being adopted by the industries for enhancing the shelf life of the formulations. An attempt is made to explore the knowledge of shelf life and stability data along with the importance of standardization through this article.

Keywords: Shelf life, stability data, *Charaka, Sushruta*, Ayurvedic industries

Introduction

Stability testing of herbal drugs is a challenging risk, because the entire herb or herbal product is regarded as the active matter, regardless of whether constituents with defined therapeutic activity are known^[1]. The purpose of a stability testing is to provide proof on how the quality of the herbal products varies with the time under the influence of environmental factors such as temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial contamination, trace metal contamination, leaching from the container and to establish a recommended storage condition and shelf-life. Ayurvedic therapeutic system includes various types of dosage forms depending upon its shelf life *viz.*, *vati* (tablet), *churna* (powder), capsule are the solid dosage forms. *Kwath* (decoction), *asava* and *arista* (alcohol containing preparation) as liquid preparation. Some semisolid preparation like *kalka* (paste) and *avaleha*. Most of the herbal medicines contain multi-ple active agents. Due to the complex nature of herbal formulations, it becomes difficult to apply standard quality control parameters. The quality of Ayurvedic product is questioned due to lack of standard measures. Stability is interpreted as length of time under specific conditions and storage that a product will remain within the pre-defined limits for all its important characteristics (ICH Guidelines; 1993)^[2]. Evaluation of Stability data of a formulation is essential not only during production of a drug, but also to evaluate the storage condition and shelf life of existing formulations over a period of time. When the Ayurvedic products are subjected to stability studies, the dossier of an Ayurvedic product becomes more scientific and acceptable^[3]. The polyherbal formulations creates challenging task since earlier as because of its complex nature, hereby the standardization methods of such formulations need to be evaluated for assessment of stability data. Stability study ensures product quality and safety, as degradation of active ingredients may form toxic compounds. Apart from this, Real time stability study data also provide information like shelf life of newly designed drug and its storage conditions^[4]. Stability testing can be accelerated stability testing and real time stability testing. In accelerated study product is stored under stress condition i.e. at different temperature and humidity conditions. During this period its physico-chemical and microbiological conditions are monitored at predetermined time interval.

Importance of stability testing

It evaluates the efficacy of a drug for specific period of time. Stability studies are used to develop suitable packaging information for quality, strength, purity & integrity of product during its shelf life.

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It is used for determination of the shelf life. Several studies on stability testing were conducted earlier and those are as follows:

Gajanan B. Bhagwat and etal had conducted “Stability study and Evaluation of Ayurvedic formulation- Anoa cream” on December 2017, there he found no significant variation after six months of the study period and the product can be stored up to six months.

Deepa P and et.al., had conducted “Comparative stability study of formulated Ayurvedic health supplement and marketed product” on 2012 and their she found that the formulation could be preserved at low temperature as well as moderate temperature. When compared to the marketed formulation, the poly herbal formulation shows a very good response in stability studies.

Biswajyoti Patgiri and etal had conducted “Evaluation of stability study of Ayurvedic formulation – *Rasayana Churna*” on January 2014 and their he found that *Rasayana Churna* was suitable at accelerated condition up to 6 month storage. it can be extrapolated that shelf life of *Rasayana Churna* is 25.12 months (2.09 years) for countries which comes under climatic zone I & II and 16.60 months (1.38 years) for countries which comes under climatic zone III & IV. Real time stability data of *Rasayana Churna* showed very good stability up to 1 year.

Challenges in Stability testing of herbal medicinal product

Evaluating the stability of Ayurvedic formulations, presents a number of challenges when compared to chemically defined substances. In particular:

1. Active constituents in Ayurvedic formulations consist of complex mixtures of constituents and in most cases the constituents responsible for the therapeutic effects are unknown.
2. The situation is further complicated when two or more herbs are incorporated in Ayurvedic formulations. In many cases where combinations of herbs are present in Ayurvedic formulations, they have similar constituents and this gives rise to even more analytical challenges.

As part of a total quality control strategy for Ayurvedic formulations, Ayurvedic formulations, a set of test criteria including qualitative and quantitative parameters has been recognized as quality indicating. With regard to stability tests, chromatographic fingerprints as well as appropriate methods of assay via marker substances represent the fundamental part of this concept, laid down in shelf-life specifications. Notwithstanding the appropriateness of this approach, its realization is often associated with analytical problems and high costs.

Predictable changes in Ayurvedic formulations

Several predictable changes may occur in herbal medicinal product during storage and in shelf-life determination: Hydrolysis, Oxidation, Racemization, Geometric isomerization, Temperature, Moisture and Light.

Packaging

As per the reference in Charaka Samhita, the Ayurvedic formulations are need to pack in such a way that the packaging material shouldn't interfere with the chemical, physical and biological properties of the drug packed inside^[5]. So, the packaging material has a great role in obtaining a suitable purity and potency product for a specified period. The package should have ability to conquer the product from

hazardous environmental conditions, stress, vibration, oxidation microbial growth etc. Till date there are various packaging material introduced in the market which are being used for different Ayurvedic formulations like churna, taila, kwath, asava, aristha, vati etc. Some glass material is also used for the photosensitive product. Hereby the packaging material quality is solely responsible for the product quality. Stability studies hereby utmost importance for all these Ayurvedic formulations as because of its several probable factors for its degradations. For all the polyherbal formulations, their need to be developed standardization methods for assesment of its quality control parameters.

Storage conditions

The most important point in the evaluation of the stability data is the storage conditions of the product. Quality of crude drug material, plant preparations and finished products depend upon the content variation and stability during storage.

Accelerated stability study and real time stability study is conducted as per ICH guideline Q1. A (R2)^[6].

- Accelerated stability: Temperature: 40 °C ± 2, Relative Humidity (RH): 75% ± 5
- Real time stability: Temperature: 25 °C ± 2, Relative Humidity (RH): 60% ± 5

The change is observed during 6 month for accelerated stability and 1 year for real time stability study at an interval of 0,1,3,6 and 12 months. Real time stability is comparatively carried out to evaluate actual degradation rate of the product with respect to accelerated condition.

Discussion

There is no any specific guidelines till date for stability/shelf life estimation of Ayurvedic formulations from Government organization except two Gazette notification issued by Govt. of India on 20th October 2009 and 24th November 2015. In this notification the Ministry of AYUSH deptt. of Health and Family Welfare has implemented the rule namely Rule 161(B) to display the date of expiry of ASU drug and propose shelf life of different Ayurvedic formulations like churna, vati, taila, asava, aristha, lepa etc. Here in this guideline there is not any methodology for the estimation of shelf life of all these Ayurvedic formulations^[7, 8]. In ancient period there was no industrialization and *Vaidyas* used to prepare the medicine for their patient. The formulation that *Vaidyas* prepared was only for getting desired effect on that time only and they need not to think for a greater shelf life. But for to-days era of globalization there is a need of large scale production and retention of samples for the healthcare of greater numbers of people. Hereby for getting the desired therapeutic effect, the stability and standardization is highly essential.

There is a need of scientific studies to establish detailed guidelines for conducting stability studies and standardization method for varying Ayurvedic dosage formulations. The container closure along with the storage conditions also need to be reestablished as for different ingredients it may shows interaction with packaging materials and the patient will not get the desired therapeutic value.

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