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Iqra Akram Regu

Department of Ilmul Advia
(Pharmacology), National Institute of
Unani Medicine (NIUM), Kottigepalya,
Magadi Main Road, Bengaluru,
Karnataka-560091, India

Abdul Wadud

Department of Ilmul Advia
(Pharmacology), National Institute of
Unani Medicine (NIUM), Kottigepalya,
Magadi Main Road, Bengaluru,
Karnataka-560091, India

Shaista Perveen

Department of Ilmul Advia
(Pharmacology), National Institute of
Unani Medicine (NIUM), Kottigepalya,
Magadi Main Road, Bengaluru,
Karnataka-560091, India

Shamim Irshad

Department of Ilmul Advia
(Pharmacology), State Unani Medical
College, Prayagraj, UP, India

Correspondence:

Abdul Wadud

Department of Ilmul Advia
(Pharmacology), National Institute of
Unani Medicine (NIUM), Kottigepalya,
Magadi Main Road, Bengaluru,
Karnataka-560091, India

Email: drwadud87[at]gmail.com

Age of Unani drugs and the concept of shelf-life: A comparative assessment

Iqra Akram Regu, Abdul Wadud*, Shaista Perveen, Shamim Irshad

ABSTRACT

It is a legal obligation for all conventional pharmaceutical products carrying the dates of manufacture and expiry on the label. The period between these two dates is called the 'life period' or 'shelf-life' of a product. It is the time over which the quality of a product remains within specifications by which the efficacy and safety of the product can be assured. Shelf-life is applicable on Unani drugs too, however, not the same as the conventional pharmaceuticals. As long before Unani physicians have proposed the concept of *Aamare Advia* (ages of drugs) mainly for single drugs. In true sense, the two concepts are the same but the way of estimation of 'shelf-life' is different. In conventional pharmaceuticals, it is considered in terms of stability studies whereas in Unani medicine it has been prefixed. The present review will explain these concepts with a comparison.

Keywords: *Aamare Adevia*, Age of drugs, *Ilmul Advia*, Shelf-life, Stability.

INTRODUCTION

Science of medicine has been in different civilizations, therefore, named as traditional medicine, folk medicine, tribal medicine, oriental medicine etc. The Hellenistic origin of Unani medicine has remained the most popular one. This system is based on the teachings of Greek, Arab and Indian physicians. The basic concepts that laid the foundation of this medicine are cosmogonic. Hippocrates is believed to be the first one who gave medicine a scientific basis. With the advent of time, the concepts and approaches towards illness and disease changed.

Ilmul Advia has been the foremost subject of Unani medicine. It deals with the study of the effect of drug and food on the human body. Besides, it includes rules that are associated with anything taken as drug and food. ⁽¹⁾ *Aamare Advia* is a concept, which is related to the part governed by the rules.

Undeniably, herbal drugs are in use for over the longer periods. Alternative medicines still face tribulations, the crucial one is the quality of herbs used as a drug. There are issues with cultivation, harvesting, quality preparations and processing that make herbs shoddy. Most drugs are prescribed without any knowledge of their potency at the time of prescription. Therefore, it is important to know how to protect the drugs from annihilation.

Conventional medicine talks about the age of drugs in an expression of shelf-life, which is the time during which the drug has decreased to 90% of its initial concentration or remains stable (retain > 95% potency) under specified storage conditions. ⁽²⁾ It indicates the assurance of the efficacy, safety and esthetics of the product. ⁽³⁾ It is also a legal obligation. Since, conventional medicine has no concept of the single drug as traditional systems of medicine have. Rather, it considers isolated compounds, which are a single chemical entity. The conventional concept of shelf-life of drugs is objective and can be measured at parametric scales.

Unani physicians have long before proposed the concept of *Aamare Advia*. Their clinical experience, imagination, intuitive work, rational behavior towards drugs suggested that when should a part of plant be collected. It is said that as long as the drug remains intact on its plant, its life thrives for a long period, but once detached the life shortens. ⁽⁴⁾ Unani concept of shelf-life is a bit different from the conventional concept. It is the time between the intactness of the plant part with the origin and the time with which the quality of a drug remains within specifications. Unani physicians also say that nature has fixed time of collection for every single part of a plant. Collection at those fixed timings indicates that the part is maximally potent and efficient. Collection done earlier or later makes the part futile". ⁽⁵⁾ Unani physicians

have fixed age of most parts of drugs based on their experience provided the drugs are stored under prescribed conditions. According to Unani concept, the shelf-life of drugs is subjective and can't be estimated at parametric scales.

Today, scientists say that herbal drugs are collected strictly when they contain the maximum concentration of active ingredients. The advantage of on hand environmental condition is also considered while collecting drugs. This means that drugs have a natural capability to act promptly for a particular time, after that it shows least or no action. This can be correlated with the Unani concept of the relation of activity of drugs with planets, which may be nothing but a change in the environment with the movement of planets influencing the growth of the plant and thereby constituents.

Ancient Unani scholars have clarified that drugs don't prove effective all times. They believed that when a planet is ascending, the effect seems to appear in maximum and *vice versa*. This has led to a moot point that every drug can be under the influence of season or environmental condition. They suggested collection of the drug from its original habitat and that too in suitable environmental condition to produce good results. Practically, the concept does not seem to be applied because we can't get such drugs with maximum content. Drugs are used when required. Therefore, fresh drugs are stored in suitable conditions.

Although, shelf-life has been found applicable on the finished contemporary pharmaceuticals. For Unani, it is applied on single and compound drugs both. If, after collection, the drug remains stored for any length of time, there appear changes in the physicochemical properties. Such changes are brought up by high temperature, presence of moisture in the storage, and sunlight etc. Some of these factors further give rise to the growth of microbes, the secondary factors, which further deteriorate the stored drugs. The change in the properties brings alteration in the chemical structure of many active constituents. Besides, we do not know how much the drug has already spoiled after procurement. It is difficult to know the potency and the age of every drug. Whatever has so far been said by the ancient physicians is based on their experience. In short, it may be said environmental factors can affect the age of drugs. There is a thumb rule that unless the drug changes in colour, taste, odour, it is considered to be useful.⁽⁶⁾ There is no objectivity in confirming the potency and stability of a drug and for how long it is efficient enough to serve the purpose.

Help from new technology has been taken that has satisfactorily assessed the condition of drugs concerning the conditions to which almost all drugs come across. One such method /model is stability study. An environmental chamber called a climatic chamber or climate chamber is an enclosure used to test the effects of specified environmental conditions on biological items, industrial products, materials, and electronic devices and components. In this model, a fresh drug is allowed to undergo critical conditions like increased temperature, pressure, excess light, and high humidity. The drug will be kept for a certain period and all these increased environmental conditions will accelerate the process and bring early deterioration. This technology has helped in the determination of deterioration in a short time. After that, the same drug is assessed by various physical, chemical, biological and analytical processes that will determine the changes in parameters.⁽⁷⁾ The shelf-life is determined by real-time stability studies or by extrapolation from accelerated degradation studies. The expiry date does not mean that medicine has lost potency or became toxic. But, the quality of the medicine is not assured beyond the expiry date and the manufacturer is not liable if any harm arises from the use of the product.² Loss of potency beyond the life period of the formulations depends on the drug as well as the storage conditions. High humidity and temperature accelerate the degradation of many drugs. Though the majority of medicines, especially solid oral dosage forms, remain safe and active years after the stated expiry date, their use cannot be legally allowed beyond the date.⁽²⁾

METHODOLOGY

The paper is a review of information on the age and stability of the drug in Unani and Conventional medicines. A search was made to collect the available information from classical Unani books, Contemporary reference books, journals, articles, periodicals, and other published works. The literature from Unani medicine is cited as a reference wherever they are quoted. The keywords used in the classical books for the search was as *Aamare Advia* and shelf-life. The information was categorized and kept at suitable places in introduction, literature review and discussion sections.

Literature review

In Unani medicine, the word 'shelf life' of drugs is not directly mentioned as has been in conventional medicine. Instead, a term *Aamare Advia* (ages of drugs) is found in some Unani books. The issue with shelf life and *Aamare Advia* is whether they can be used interchangeably or not. To some extent, they may be, if seen in a contemporary perspective, but at times, not because shelf -life is assigned to a conventional pharmaceutical after stability studies, whereas the age of single herbal drug is prefixed. However, the shelf life may be applicable for finished herbal products. There are two types of plants, one which thrives for a few years and the other one, which is seasonal and does not survive for more than a year. After a certain period, there appear some changes that alter the colour, odour, taste etc. of the drug. Physicians suggest the use of these drugs before such changes are visible.⁽⁵⁾

Among the various types of single drugs, one should select the drug which has peculiar odour and taste.⁽⁴⁾ It is mentioned that no drug should have directly experimented on the human body unless one is sure about its organoleptic properties in a way that if taste appears to be unpleasant and one feels repulsion, it means it is spoiled. Similarly, if the taste is unpalatable, it indicates the drug spoiled.⁽⁸⁾ For plant origin drugs, some Unani physicians have said that as long as the drug continues to remain intact with its main body, it is exquisite and survives for a longer period but once detached, its life shortens and hence storage becomes important. Similar suggestions were made for the storage of root, stem, flower, bark and other plant parts. Since, drugs have natural propensity to lose efficacy and become weaker, therefore, collection and storage are playing pivotal roles. It is said that collection of a drug depends on its natural habitat, geographical distribution; a definite period and a particular season.⁽⁹⁾ here are three sources of plant origin drugs, *viz.* cultivated, grown in deserts and grown on hills/ mountains. Although all have almost similar, it is said that hilly plants are more potent.⁽¹⁾

The purpose of storing drugs is to prevent them from degradation and an intention to maintain their potency. The purpose of converting single drugs into certain formulations like tablets and pills is also to store drugs for long.⁽⁶⁾ There is a belief that once a dried drug is powdered, mixed with some gums which act as binders and then shaped into a tablet form, the age of the drug in its tablet form is many times more than a simple powder form. Tablet lasts for at least one year while powder lasts for only two months.⁽¹⁾ For storage, moisture-free spaces are preferred, where temperature, as well as moisture, are moderate. Dust, dirt, or any other kind of filth should not be there. The age of the plant is playing a substantial role which regulates the total quantity of active constituents to be present in the drug and also determines the relative proportions of other components.⁽¹⁰⁾ Evidences and researches have proved that the composition of a number of secondary metabolites in the plant show diurnal variation i.e. vary throughout the day and night. If the overall amount of alkaloid or glycoside does not change to any level but they may interchange.⁽¹¹⁾ This is the reason why there is a need for all pharmaceutical products to carry the date of manufacture and date of expiry on their label.

Comparison of concept of age in Unani and conventional medicine is focused in this paper, especially reviewing the concept of the age of crude drugs as per the Unani literature when sophisticated devices were

not invented and the conventional medicine which determines ages of drugs with the help of certain innovative ideas. However, *Amare Advia* has included all aspects related to the age of a drug like its period of efficacy, potency, degradation by environmental factors etc. For them, morphology and organoleptic characters of the drug were the only tools known. Diminished color, odor, deformed texture was an indication that the drug is not to be used further. Organoleptic evaluation of the age of herbs since ancient times holds a distinctly limited value now. Ancient physicians differentiated species of mentha, clove and cardamom by smell. But smell and such other characters are not enough to know the rate at which the drug has degraded. Age had no proper definition for them.

“With the best management practices under a less limited environment, it is possible to achieve the highest plant yield. Maximum yield achievable under the production system includes the best of all controllable factors needed to produce the highest possible yield. The yield maximum generally varies with climate, soils and growing seasons. In a place where all the parameters are optimum during a perfect growing season, maximum yield should be approximate to the maximum potential yield.”⁽¹²⁾

The present scenario exhibits a greater demand for herb-based drugs, the reason is an alarming increase in the side-effects, addiction and adverse reactions associated with the conventional drug. Apart from these, there exists one important drawback linked with conventional medicine and that is, escalating prices of the drug. So, as per the requirement of our health systems, it lays some amount of emphasis on Herbal medicine. Herbal medicine on all together can't be proclaimed as the safest form of the drug. They are safe in terms of their limited or lesser adverse effects. With these drugs, the matter of concern is their age. Crude herbal drugs consist of organized as well as non-organized parts like leaf, flower, seed, wood, bark, root, oils, gums etc. Ancient physicians determined the age by organoleptic characteristics which were the only method of knowing the identity and quality of the drug. Description of color, odor, taste, consistency was some open features. Ancient physicians described the general conditions of the drug-like size, shape, markings on the outer, inner surfaces, fractures etc. They differentiated species of *Mentha* by smell only. Similarly, the quality of some volatile oils containing drugs like clove and cardamom was also determined by their smell. Age had no proper definition for them but they gave preference to fresh herbs over older herbs. In this modern era, we know age by knowing the stability of a drug.

Now scientists have been able to fix the definite life for a drug. Accelerated stability chambers have facilitated and lessened the labour and time. The quality and potency of a drug can now be easily determined. Stability for a drug as per the modern definition implies its stability of pharmaceutical agents which determines the potency and efficacy of a drug over the period. Less stable drug means potency and efficacy for little time. It refers to the loss of uniformity, loss of elegance, reduction in bioavailability, production of toxic contents, or breakdown of drug. Determining the stability or age of a drug gives a clue for how long a drug should be used. “Stability of pharmaceutical products refer to the capacity of the products or a given drug substance to remain within established specifications of identity, potency, and purity during a specified period.”⁽¹²⁾ One of the requirements of the material to be used as a drug is that they should possess the maximum activity and thus should contain a maximum percentage of active chemical constituents.⁽¹¹⁾ For this reason, drugs are purposely cultivated because, in the process of cultivation, attention is paid to the number of things like the selection of seeds or root, type of soil, climate, weather, light, temperature, moisture, rainfall, and many other growth factors. Any drug obtained under the supervision yields a good amount of required ingredients.

DISCUSSION

Plant origin drugs are leaves, roots, seeds, flowers, fruits, extract, gum, bark, oil/fat, milk/latex, branch, shoots, whole plant, salt, proteins, and active constituents. To obtain these drugs, there is a general rule that

they should be collected from a plant which is grown to the fullest.¹² For a collection of the drugs from their source, the seasons are usually mattered of considerable importance, as there is a shred of evidence that the amount and the nature of the active constituents do not remain constant throughout the year.⁽¹³⁾ Drugs are collected during different seasons, at a particular time of the day and a definite stage of development (Ghani). Knowing the type of crude drug and area of collection, the drugs are collected when they contain the maximum concentration of active ingredients. The environmental conditions are also taken into consideration while collecting the crude drugs.⁽¹³⁾ Drugs are to be collected in a specific time like roots, branches when the plant is completely grown, leave when they seem to be in their maximum size and no changes appear in them, flowers are collected when they bloom to the fullest. Dried flowers are not collected because they have already undergone certain changes. Fruits are collected when they are ripe, seeds when their outer covering is intact and is filled with the content (Maghribi, 2007).⁽¹⁴⁾

Before these crude drugs are made available in the market, there is a need for some preparations and the reason for preparation is to stabilize them while being transported or stored and also mark the absence of foreign organic or non-organic matter. Such preparation of crude drugs takes care of drug elegance.⁽¹²⁾ Drugs with natural colour, odour, taste are considered most potent like grass which can thrive better with its natural characters for about one to two years after that changes appear.⁽¹⁵⁾ Only when we understand the concept of the potency of a drug, we come to know how important it is to protect these drugs. When low potency drugs are prescribed, we wonder at their reduced efficacy and results (Majoosi, 2010). It is said that as long as the drug remains intact with its plant, its life is long and it can thrive for long period but once detached, its life shortens and only then storage plays its role.⁽⁴⁾

Gum show potency for 3 years, extracts shows it for little less time than gums. Flowers and leaves are potent within a year only. Milk from various plants show different periods of expiry like opium lasts for 50 years, Farfiyun for 40 years, Scammony for 20 years, thus marking their average period of activity for 10 years. Among oils, those with cold-wet temperament show their potency till 3 weeks while oils with hot-wet or hot-dry last for 1 year and after that become rancid, with an exception of balsam oil which has a long period of potency and olive oil lasting for 4 years. Different flowers show different ages. Oily and covered seeds are potent for a year while non-oily and uncovered ones last for a week only, less oily seeds have a potency of 2-3 years. Leaves remain potent for 2-3 years only if provided with proper storage conditions otherwise their potency lasts for one year only. The potency of barks, roots, branches usually depends on their structure- hollow or solid, soft or hard, flexible or rigid. To preserve each drug, first, it is important to dry them in the shade so that it remains moisture-free. A little amount of sunlight can be given to dry them ensuring that drug contains no more moisture.⁽⁵⁾ In case, the enzymatic action is needed, slow drying at a moderate temperature is necessary and if not, then drying should take place soon as after the collection.⁽¹⁰⁾ Preservation of crude drugs needs sound knowledge of their physical and chemical properties. Good quality of the drugs can be maintained if they are preserved well. Apart from protection against adverse physical and chemical changes, the preservation against insects or mould attack is also essential.

Some contents of the drug are stable to the temperature and sunlight, and the drugs can be dried directly in the sunshine.⁽¹⁾ Drugs containing volatile oils lose their aroma if not dried or if the oil is not collected from them immediately. All drugs are liable to develop molds also (William, 2008)⁽¹⁰⁾ storage, moisture-free spaces are preferred, where temperature, as well as moisture, are moderate. Dust, dirt, or any other kind of filth should not be there.⁽⁵⁾ If the flowers and leaves are supposed to retain their aroma and color respectively, then they should be subjected to rapid drying keeping the temperature in mind which should not destroy the constituents and the physical nature of the drug. As a precaution, leaves, herbs, flowers are dried at 20-40^o C while barks, roots at 30-65^o C.⁽¹⁰⁾

in Unani Medicine and that of conventional medicine are not the same but up to some extent. The Unani concept of age is based on the change in the morphological as well as organoleptic characters. By observing these parameters, the Unani physicians determined and fixed ages of different parts of the plant, mineral or animals. Physicians of those times concluded that up to any particular time, these characters maintain their maximum level and till then the drug is said to be potent. Once these characters show annihilation, the drug loses its potency too. These parameters of determination of age are subjective and don't justify how by observing the morphological and organoleptic characters one fixes the age of a crude drug. In Conventional Medicine, the concept of age is an expiry of the drug which means that the drug has become less potent and cannot be further put to use. They have given certain parameters by which expiry of the drug can be measured by knowing the shelf-life. Before marketing of the drug, all conventional drugs pass through stressed conditions which usually the drugs come across like at medicinal stores or houses. The shelf-life is calculated by keeping the drug in the stability chamber under stress conditions of high temperature, humidity, pressure. The changes appearing in the drug are measured at suitable intervals.

CONCLUSION

Aamare Advia is a basic concept, whereas shelf-life is much accurate and designed way of age determination. Although, the methods of shelf-life can't be fully implemented on Unani drugs, but advantage can be taken of.

Conflict of interest: None

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