Unani Medicine and Stability Studies – A Short Communication

Ahmad Husain*, G.D. Sofi², Tajuddin³, Shobha Rani R.H.⁴, Mueen Ahmed K. K⁵

¹H.A.H.Unani Medical college and Hospital, Dewas, M.P., India. ²National Institute of Unani Medicine Kottegopalaya Bangalore. ³Department of Ilmul Advia, AMU, Aligharh, India. ⁴⁵Al-Ameen College of pharmacy Bangalore.

Unani drug formulations are being use since the time of Hippocrates. Unani Hakeem mentioned the Stability periods of Unani formulations based on their keen observations and organoleptic parameters. Therefore, the acute observations of the Unani classical authorities need to be substantiated with empirical evidence using scientific methodology.

Key words: Unani drug formulations, Hakeem’s, organoleptic parameters, scientific methodology.

INTRODUCTION

As we observe in our routine life that all objects get spoiled after a specific period. All the living beings go through a cycle of birth, growth, reproduction and death. All the non-living substances that are grown or manufactured go through a life span in which they influence and are influenced by their environment. Everything made by human hands from the sublime Parthenon to the trivial milkshake is subject to decay. There is no existence of such a substance in the world, which is imperishable. Either it is our house where we resides or house hold substances like vegetables, fruits, rice or wheat, which we use in our daily routine life. Man is dubbed as the “most eminent of created beings” also has a life span after which he gets perished.

Pharmaceuticals are no exception to this general statement. If there is any functionally relevant quality attribute of a drug product that changes with time, evaluation of this change falls within the purview of the pharmaceutical scientists and regulatory authorities who quantify the stability and shelf life of drug product. The rate at which drug products degrade varies dramatically. Some radiopharmaceuticals must be use within a day or so. Other products may become, if properly stored and packaged, retain integrity for a decade or more, although in many jurisdictions the maximum shelf life that a regulatory agency will approve for a drug product is five years. This restriction is hardly an onerous one, since even for a product with a five-year shelf life it is probable that over 95% of the product will sold and used within thirty months of manufacture, providing all involved in the distribution process obey the first law of warehousing: FIFO-first in, first out.

HISTORY AND UNANI MEDICINE STABILITY STUDIES

History of Greek medicine started with Pericles (561-430 BC) but very much distinguish figure was Hippocrates (460-377 BC), a member of the family of Asclepius (Asqualibuis). Hippocrates called as the father of medicine gave the fundamentals of medicine. After the Hippocrates; Galen another prominent physician gave the scientific views to these fundamentals. Galen (Jalinoss) (131-201AD) who was attached to the roman court and all time influential writers was the first who mentioned about the shelf life of Sufoof (powder). Ghulam Jelani has mentioned a citation of Jalinoss in his book Kitabul Murakkabat that all powder retains their potency not more than two months.

During the stint of Galen (Jalinoss) in second and third century AD Greek medicine transcended to its apotheosis but after Paul of Aegina (615-690) who was the last of compiler of Greek medicine descended to a stage of inactivity and then traveled to Arab world where it was preserved and nurtured. The first channel through which Greek medicine reached to the Arab world was the school of Alexandria (Askandria) and secondly the school of Jundishapur of Persia. In this connection the first book that...
originally written in Arabic language was *Firdausul Hikmat* by Abul Hasan Ali Bin Sahel Rabban Tabri in ninth century A.D., had mentioned about shelf life of *Tiryaqe Akbar*. According to him *Tiryaqe Akbar* has efficacy up to 30 years and even more.\(^5\) Abubakr Mohammad bin Zakaria Razi (865-925 A.D.);\(^6\) known to the west as Rhazes, was the most celebrated and most savant Arabic medical writer. Razi had mentioned shelf life of several single drugs in his book *Al Havi Fit Tib*. After Razi another Arab physician Ali Ibn-e-Abbas Majoosi (930-994 A.D.), mentioned extensively about the shelf life of single as well as compound Unani formulation in his compilation *Kitab-Al-Mulâ“* that is famous with the name *Kamîl-Al-Sanâ“. He mentioned the shelf life of *Aqraas Ashqueel, Aqraas Afaai, Tiryaq Arba*, and *Tiryaq Shalisa* from two months to two years and shelf life of *Majoon kibrit* from six months to three years. The great philosopher, thinker and prominent physician of Arabic medicine Shaikh-Arrais-abu Ali Bin Sina (375-428 A.H.), has illustrated the stages of potency and degradation of *Tiryaq-e-Faroque*.\(^8\)

Other profound Unani physicians like Sharfuddin Ismail Jurjani (531 A.H.);\(^4\) Mohammad Ayyub Israeli, Mohammad Hadi Khan Mohammad Husain, Hakeem Akbar Arzani (1722 D.);\(^\) and Kabiruddin (1894-1976 AD)\(^6\) noted down the shelf life of certain Unani compound formulations. The observations related to Shelf life of drugs are seen originally in the text of Mohammad Hadi Khan Mohammad Husain.\(^9\)

The other writers have just followed the trends of their predecessors like Hkm Kabeeruddin and Azam Khan. Recently, it has become mandatory to evaluate stability studies of drugs to ascertain their purity and efficacy over time. Obviously, loss of drug constituents is of major importance in the stability studies of many pharmaceutical products. Unfortunately, one sometimes gets the impression that some regard this as only adverse effect of drug product stability. This is, of course, not true and for some products, losses of active ingredients are not critically variables that determines shelf life. However, it is certainly true that for many products loss of potency is of major importance. In general, we regard any product that contains less than 90% of label claim of drug as being of unacceptable quality. Therefore, for many drugs products, determination of the time that elapses before the drug content no longer exceeds 90% (when the product is stored in conformance to label instructions) is an essential element in determining shelf life. The long term testing should cover a minimum of 12 months’ duration on at least three primary batches at the time of submission and should continue for a period sufficient to cover the proposed re-test period. Additional data accumulated during the assessment period of the registration application should submit to the authorities if requested. Data from the accelerated storage condition and, if appropriate, from the intermediate storage condition can be used to evaluate the effect of short term excursions outside the label storage conditions (such as might occur during shipping). Long term, and accelerated stability studies and, where appropriate, intermediate storage conditions for drug substances should evaluated in detail. The general case applies if the drug substance is not specifically cover by a subsequent section. Alternative storage conditions can be use if justified. If long-term studies are conducted at 25°C ± 2°C/60% RH ± 5% RH and “significant change” occurs at any time during 6 months’ testing at the accelerated storage condition, additional testing at the intermediate storage condition should be conducted and evaluated against significant change criteria. Testing at the intermediate storage condition should include all tests, unless otherwise justified.\(^11,12,13\)

As shown in above discussion that in most of Unani classical literatures have mentioned the stability periods of formulations so we have to evaluate them based on modern stability parameters.

**CONCLUSION**

Unani physicians have used Unani formulations since centuries, by their keen observation and experience, these authorities have noted about the expiry dates of various dosage forms. Presently, stability studies are a must for registrations of a drug product and to ensure the quality of a finished product, thus assessing stability of a product in itself is a foremost necessity.

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