

Invited commentary

Need of standardization and quality control of herbal drugs in this Era

Rais-ur-Rahman

Ayurvedic and Unani Tibbia College, Ajmal Khan Road, Karol Bagh, New Delhi, Delhi-110005.

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“Health for all” is a dream and a goal which humanity at large shares and strives for, unfortunately, it has been proven without doubt that modern pharmaceuticals are and will remain out of reach for a large proportion of the human population for the near future. This has created an appreciation and a need for the use of other sources of human knowledge to provide common health benefits. Alternative and traditional medicines, largely herbal in nature, are now regarded as important but underutilized tools against disease. (Swati Manik, Reference ID: Pharmatutor-Art-1643).

The use of herbs as medicine, is the oldest form of healthcare, known to humanity and has been used in all cultures throughout history (Barnes *et al.*, 2007). Early humans recognized their dependence on nature for a healthy life and since that time humanity has depended on the diversity of plant resources for food, clothing, shelter, and medicine to cure myriads of ailments. Led by instinct, taste, and experience, primitive men and women treated illness by using plants, animal parts, and minerals that were not part of their usual diet. Primitive people learned by trial and error to distinguish useful plants with beneficial effects from those that were toxic or inactive, and also which combinations or processing methods had to be used to gain consistent and optimal results. Even in ancient cultures, tribal people methodically collected information on herbs and developed well-defined herbal pharmacopeias. Physical evidence of the use of herbal remedies some sixty thousand years ago has been found in a burial site of a Neanderthal man uncovered in 1960 in a cave in northern Iraq (Solecki, 1975).

Herbal drugs are widely used since ancient times as therapeutic ailment against variety of diseases throughout the world. In spite of the great advances observed in modern medicine in recent times, plants still play a vital role to healthcare (Calixto *et al.*, 2000). Ethnomedicines have become significantly more popular around the globe because of their lesser side effect and effectiveness. In addition, they are also the source of chemical intermediate, needed for the production of many drugs. India has contributed its knowledge of Unani and Ayurvedic system of medicines to develop herbal drugs. The World Health Organization (WHO) has also recognized the benefits of drugs, developed from plants (Abat *et al.*, 2017). Herbal medicines are used frequently in various traditional system of medicines like Ayurveda, Unani, Chinese medicine, Naturopathy and Homeopathy. These systems describe medicinal

plants which were used as therapeutic ailment as early as 3,000 BC (Joseph *et al.*, 2012).

Herbal drugs include herbs, herbal materials, herbal preparations and finished herbal products. Herbs include crude plant materials, such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes, *etc.* Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various procedures, such as extraction, fractionation, purification, concentration, or by steeping or heating herbal materials in alcoholic beverages and honey. Finished herbal products may contain excipients in addition to the active ingredients. The task of laying down standard for quality control of herbal crude drugs, their products and formulations involve biological evaluation for disease area, chemical profiling of the material and laying down specification for the finished product. WHO emphasized the need to ensure quality control of medicinal plant products by using modern technique and by applying suitable parameters and standards (WHO, 2000).

Modern system of medicine is based on experimental data, toxicity studies, preclinical and clinical studies. But, Pharmacopoeial standards on raw material / finished products are not available. Standardization of herbal drugs is decisive to evaluate the quality of drugs, based on their bioactivity, phytochemical, physical, chemical, *in vitro* and *in vivo* parameters. The quality assessment of herbal formulations is of paramount to justify their acceptability in modern system of medicine (Sachan *et al.*, 2016).

Currently, there has been great demand for plant derived products as food supplement, nutraceuticals, cosmetics and medicinal products in the world (Sagar *et al.*, 2005). In order to obtain good quality herbal product, carefulness should be taken in the proper way from identification of plants, season, area of collection, their extraction, purification and rationalizing the combination in case of polyherbal drugs (Archana *et al.*, 2011) and, it has become essential to develop reliable, specific and sensitive quality control methods, using a combination of classical and advance analytical techniques. Standardization is an essential measurement for ensuring the quality control of the herbal drugs (Kumari, 2016).

Standardization and quality control of herbal drugs include, pharmacognostic evaluation (colour, odour, taste, texture, size, shape, microscopical characters, and histological parameters), chemical and physicochemical parameters (limit tests, chemical tests, foreign matter, total ash, acid-insoluble ash, swelling and foaming index, assay, successive extractive values, moisture content, viscosity, pH), *etc.* Other parameters such as disintegration time, friability, hardness, flow capacity, flocculation, sedimentation,

Author for correspondence: Dr. Rais-ur-Rahman
Professor, Ayurvedic and Unani Tibbia College, Ajmal Khan Road,
Karol Bagh, New Delhi, Delhi-110005, India
E-mail: dr.rahman002@gmail.com
Tel.: +91-9313980776

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alcohol content, *etc.* However, chromatographic and spectroscopic analysis includes TLC, HPLC, HPTLC, GC, UV, IR, FT-IR, LC-MS, GC-MS, *etc.* (WHO, 1996; Kamal *et al.*, 2015; Mallick *et al.*, 2015; Singh *et al.*, 2014; Ahmed *et al.*, 2015; Zahiruddin *et al.*, 2017; Kamal *et al.*, 2016) as well as determination of contaminants include aflatoxins, pesticides, heavy metals and microbiological load (WHO, 2011).

Several pharmacopoeias from the different countries such as United States Herbal Pharmacopoeia, Chinese Herbal Pharmacopoeia, British Herbal Pharmacopoeia, British Herbal Compendium, Japanese Standards for Herbal Medicine as well as the Unani and Ayurvedic Pharmacopoeia of India, lay down monograph for herbs and herbal products to maintain their quality in their respective nations. Government of India recommends basic quality parameters for frequently used common herbal drugs brought out from Unani and Ayurvedic Pharmacopoeia of India. WHO encourages, recommends and promotes herbal medicine in national healthcare programmes because these drugs are easily available at low cost, safe and people have faith in them. The WHO assembly in number of resolutions has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying suitable standard. Quality control of crude drugs material, plant preparations and finished products and, their shelf life, stability, safety assessment and assessment of efficacy by ethnomedical information's and biological activity evaluations. The bioactive extracts should be standardized on the basis of active principles or major compounds along with the chromatographic analysis, *viz.*, TLC, HPTLC, HPLC, and GC (Kamal *et al.*, 2015; Mallick *et al.*, 2015; Singh *et al.*, 2014; Ahmed *et al.*, 2015; Zahiruddin *et al.*, 2017; Kamal *et al.*, 2016) to produce a good rugged, and reproducible formulation with minimum batch-to-batch variation.

In recent years, consumption of herbal drugs has grown enormously as indicated by the marked increase in global expenditure on these products from \$20 billion in 1997 to \$83 billion in 2008 (Wah *et al.*, 2012). Consumers become more educated and enthusiastic about the safety, efficacy, and quality of herbal medicine because of potential negative outcomes, which cannot be ignored. Various, Ayurvedic medicines purchased online contained 20% detectable levels of lead, mercury, and arsenic (Saper *et al.*, 2009).

Scientific evidence of safety and efficacy is generally lacking for many herbal drugs. According to the therapeutic guide to herbal medicines of the German Commission, more than 100 herbal drugs were found to be unsafe or ineffective. Hence, more scientific studies on their quality and validation are necessary to proceed herbal drugs around the globe (Bent and Ko, 2003; WHO, 2005).

In the modern world, peoples are concerned to herbal therapies for countless reasons, the most important reason being that, it is believed that they will help us to live healthier lives. Herbal drugs are often viewed as a well-adjusted and sensible approach to healing. Individuals who use them as home remedies and over-the-counter drugs spend billions of dollars on herbal products. As such, they represent a substantial proportion of the global drug market (WHO, 2005; Gustafson, 2015). To achieve the benefit from herbal drugs, a person must take the mandatory dose over a certain period of time. Generally, it is believed that herbal drugs are safe for consumption but some herbs like most biologically active substances could be toxic with undesirable side effects (Grezes-

Beset *et al.*, 1994). A safe, well-defined and constant composition is one of the most important prerequisites for the production of a quality herbal drugs and ensuring consistent quality of products is vital for the survival and success of the herbal industry (Bauer, 1998).

The quality of herbal medicine can be improved by adopting advanced technology and conduct extensive research on source, collection, preservation, storage of drugs, formulation development, titration of dosage forms, safety, side effects, pharmacodynamic and pharmacokinetic actions, drug interactions, drug reactions, drug resistance, assessment of the safety of potentially hazardous substances in herbal medicines and the post marketing surveillance, which makes it globally acceptable (WHO, 2007).

Being worked as Advisor of AYUSH and Director General of CCRUM, I have seen many avenues of system and found that, it is essential to establish internationally recognized guidelines for assessing their safety and efficacy. This can be achieved only if the herbal products are evaluated and analyzed using modern analytical techniques of standardization such as TLC, HPLC, HPTLC, GC-MS, spectrofluorimetric and other methods. The assurance of the safety and efficacy of herbal drugs requires monitoring of the quality of the product from collection through processing to the finished packaged product. It is recommended that various government agencies should follow a more universal approach to herbal quality by adopting the uniform AYUSH guidelines on monographs. This will strengthen the regulatory process and minimize quality transgression. Further, it will be helpful in recognising our drugs safe for human use by regulatory agencies of other countries, which surely be helpful in global acceptance of Unani and Ayurvedic medicines.

In the emerging scenario of the 21st century, phytomedicine is gaining wider acceptance and importance, because it is truly a multidisciplinary areas, encompassing several disciplines. In view of the ever increasing amount of awesome research work to be carried out in the development of phytomedicines and conventional medicines from plants, a matching increase in the number of good quality, reputed journals is a requirement (Pushpangadan, 2013; Subramoniam, 2014). In this context, **Annals of Phytomedicine: An International Journal**, with a commitment to excellence in publishing cutting edge research in all areas of phytomedicine is a welcome arrival. It is gratifying to see that "Annals of Phytomedicine" is catering to the needs of scientists from different closely related disciplines by promoting the publications on plant medicines and specially by inviting the commentaries of stake holders. It is a challenging and a difficult job to run such a journal successfully. I am very happy and informing you all, working in the field of phytomedicine that Annals of Phytomedicine: An International Journal is on its way towards accomplishing its mission and bringing out this project, to its zenith.

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Professor Rais-ur-Rahman

Former Director General and Presently Advisor to Ministry of AYUSH, New Delhi, India

Professor Rais-ur-Rahman is the Advisor Unani in the Ministry of AYUSH, Govt. of India and Program Officer, Extra Mural Research Scheme, Ministry of AYUSH, New Delhi. He is also Professor in Ayurvedic and Unani Tibbia College, University of Delhi, New Delhi.

Professor Rais-ur-Rahman is born on July 1, 1960 and did his M.D. in Ayurvedic and Unani Tibbia College, University of Delhi, New Delhi, is a result-oriented Unani Physician with two and a half decades of experience in teaching and research.

Professor Rahman is a Chairman of The Purchase Advisory Committee (PAC:U) for CGHS Unani, The Unani Committee for Inclusion of Unani Medicine in International Classification of Diseases for Traditional Medicine (ICD-11), The Award Committee for deciding the awardees of CCRUM award scheme on the occasion of 1st National Unani Day, The Committees to prepare Concept Note for All India Institute of Unani Medicine, All India Institute of Homoeopathy, All India Institute of Yoga and many more.

He is a regular examiner for Under Graduate and Post Graduate for Unani Medicine courses of various Colleges in more than 12 reputed Universities in India and also supervised a number of Thesis (around 30) of Post Graduate (MD) in Unani Medicine. He has delivered lectures in various ROTP's/CME programmes for teachers/medical officers. He also participated as an expert in various national and international conferences, seminars, symposia and workshops. He is editor and member of editorial board/ advisory board of numerous reputed journal and magazines, etc.

Professor Rahman is also a recipient of various reputed awards, like Hakim Ahmad Ashraf Memorial Global Award, conferred by Hakeem Ahmad Ashraf Memorial Society, Hyderabad on 18th September 2014, Lifetime Achievement Award conferred by All India Institute of Medical Sciences (AIIMS), New Delhi on 12th January 2014 and Hakim Ajmal Khan Memorial Society on 23rd February 2017.

Professor Rahman is a Scientist, Teacher, Physician and an Administrator. As the Director General (In-Charge), Central Council for Research in Unani Medicine (CCRUM), Janakpuri, New Delhi since February 2015 to January 2017 where he made some outstanding efforts towards the betterment and upliftment of Unani Medicine.

- First time in the History of Research Councils, CCRUM has started MD and Ph.D Programme in two Discipline of Unani System of Medicine, *i.e.*, Moalijat and Ilmul Advia (14 seats in M.D. and 6 seats in Ph.D.).
- To mark the first National Unani Day, AYUSH Award Scheme was launched and awards were given in the following categories, "Young Scientist Award", "Best Teacher Award" and "Life Time Achievement Award".
- Allotment of lands for establishment of Regional Research Institute in Unani Medicine at Bhopal, Madhya Pradesh and Kadappa, Andhra Pradesh,
- Introduction of NPCDCS and Swasthya Rakshan Programme in CCRUM, where more than 300 Technical and Non-Technical manpower were employed,
- Establishment of Hakim Ajmal Khan Institute for Literary and Historical Research in Unani Medicine along with Specialty Clinic and Regimental Therapy Centre,
- Establishment of Unani Medical Centre and Regimental Therapy Centre at All India Institute of Ayurveda, Sarita Vihar, New Delhi
- Establishment of Unani Medical Centre in AYUSH wellness Centre at President's Estate.