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Integrated herbal drug development & standardization - An approach for overcoming the challenges of herbal drug industry

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Plants by virtue of its composition of containing multiple constituents developed during its growth under various environmental stresses providing a plethora of chemical families with medicinal utility. Researchers are exploring this wealth and trying to decode its utility for enhancing health standards of human beings. Herbal drugs with a billion dollar market share are being used in all the countries around the globe. One of the key factors that limit commercial utility of herbal drugs is standardization. Standardization of herbal medicines is the process of prescribing a set of standards, constant parameters, definitive qualitative and quantitative values that carry an assurance of quality, efficacy, safety and reproducibility. The quality of herbal drugs is affected by numerous factors: a) Mixtures of many constituents that make physiological responses complex yet holistic; b) Active principle (s) are generally unknown; c) Non-availability of selective analytical methods or standard reference compounds limits development of standard chemical fingerprint; d) Natural variability associated with plants both in wild & non-wild varieties; e) Differences in spectra of bioactivity in natural vs. chemo-varieties and chemo cultivars and; f) Variability in source and quality of the raw material etc. Standardization poses numerous challenges related to marker identification, active principle(s), lack of defined regulations, and non-availability of universally acceptable technical standards for testing and implementation of quality control / safety standard (toxicological testing). The present study which has been tested with herbal candidates against NDM-1 (New Delhi Metallo-beta-lactamase), MRSA (Methicillin Resistant *Staphylococcus aureus*) and radiation mitigators, proposed an integrated herbal drug development & standardization model which is an amalgamation of: a) Classical approach of Ayurvedic therapeutics (active principle guided approach); b) Reverse pharmacological approach based on observational therapeutics; c) Technical standards for complete product cycle; d) Chemi-informatics, Herbal Qualitative Structure Activity Relationship (QSAR) and Pharmacophore modeling and; e) Post-launch market analysis.

Biography

Raman Chawla has completed his Ph.D. in Toxicology from Jamia Hamdard University. He is a Scientist in the Division of CBRN Defence, Institute of Nuclear medicine and Allied Sciences. His area of expertise includes Biomedical Sciences (Drug Discovery & Development), Herbal Drugs, Herbal Informatics, Toxicology, Radiation Sciences, Molecular Biology, Biochemistry, Cancer Biology, Medical Informatics and CBRN (Chemical, Biological, Radiological and Nuclear Defence) & Medical Management Aspects of Man-made Disasters / Mass Casualty Events. He has published more than 56 papers in reputed journals with total 500 citations approximately. He has authored and edited various books on CBRN Disaster management and awareness manuals on Demystifying dreadful diseases of public concern. He has also been actively involved in fabricating the National Disaster Management Guidelines.

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