

<u>Editorial</u>

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Novel approaches for sophistication of fingerprinting methods of polyherbal formulations

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Polyherbal formulations (PHFs) are important category of traditional medicines (TMs) practiced in India. Ancient books of *Ayurveda* compiled several polyherbal combinations such as *Triphala*, *Dashamoola* etc for different therapeutic applications. *Sarangdhar Samhita* (1300 AD) has highlighted the concept of PHF based on several *Ayurvedic* principles^[1]. Plants of varying potency when combined may theoretically produce a greater result, compared to individual use of the plant, and also the sum of their individual effect. Combination of herbals may act on multiple targets at the same time to provide a thorough relief often by positive herb-herb interaction called synergism^[2]. In a disease condition, multiple organ systems are involved, therefore, drug should have a multiple targeted action. Molecules follow specific pathway and act on specific receptor, hence combination of different herbs targets different sites of action.

There is no effective machinery to regulate manufacturing practices and quality standards for PHFs so far. Anyone can buy herbal products without a prescription and might not recognize inferior product. A welldefined and constant composition of the drug is one of the prerequisites for the production of a quality drug as composition of natural products is dependent and influenced by many factors. No official standards are available for many herbal preparations, but the manufacturers, who are currently doing some testing for their formulations, have their own preliminary testing parameters. As it is very difficult to identify the presences of all the ingredients as claimed in a formulation it is important to evolve such parameter by which the presence of the entire ingredient can be identified. Evaluation of physicochemical properties in combination with various chromatographic and spectrophotometric methods can be tried to evolve pattern for identifying the presence of different ingredient. Currently many modus operandi are employed for standardization and quality control of PHFs. TLC, HPLC, GC, and HPTLC are used to determine the similarities and differences of a plant extract. These techniques hyphenated with spectroscopic techniques like MS (GC-MS and LC-MS) may work as powerful tools for standardization and quality control. These sophisticated techniques provide a chemical fingerprint as to the nature of chemicals or impurities present in the plant or extract^[3].

There are several PHFs mentioned in Ayurvedic Formulary of India (AFI), but very few having monographs on its quality standards published in Ayurvedic Pharmacopoeia of India (API). AFI Part I to III has listed 658 PHFs such as *Asava* and *Arishtas, Arka, Avaleha* and *Paka, Kvatha churna, Guggulu, Ghrita, Churna, Taila, Dravaka, Lavana kshara, Lepa,* and *Vati* and *Gutika*. But, the Part II (Formulations) Vol I to III of API has monographs for only 462 PHFs belonging different categories mentioned above. The Pharmacopoeia committee is taking efforts o develop standard operating procedures of manufacturing process to develop standards of identity, purity and strength of ingredients & PHFs. Pharmacognostic & chemical standardization shelf life studies of PHFs are undertaken at many laboratories and manufacturing companies of national repute.

Macro-microscopic examination of individual ingredients before and after compounding to the formulation may help in proving the identity of PHFs, but there will not be any indication of its quality in terms of active constituents. The physico-chemical standardisation of employing tests like loss on drying, ash values, extractive values etc may just serve the purpose of preliminary checks for PHFs as they do not indicate the exact composition of various chemicals present in the medicine. HPTLC fingerprinting of ingredients and along with the formulation will help in a comparative account of in terms R_f values of spots but on compounding herbs together most of the spots in the ingredients will vanish due to chemical interaction between them^[4].

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GCMS of PHFs is a superior fingerprint method as it will infer a qualitative fingerprint in the form of a chromatogram as well as composition compounds which are volatile on elevating temperature of the column. Variation in composition of extract might influence the fingerprint pattern, and GCMS cannot be performed for all kinds of metabolites (eg. high melting constituents). GCMS will help to understand pharmacology of the extract to some extent as identity of compounds will be established by GCMS.

To conclude, PHFs with monograph in API needs sophistication of the specified standards as the data included are quite insufficient to have exact idea of its chemical composition. A herbal / polyherbal preparation of TMs requires sophistication of fingerprint technology (SFPT) of their complex nature. Also, in the present context of increasing demand for alternative therapies, standardization of herbal medicines employing more apt fingerprinting techniques are need of the hour towards globalization. Compositional fingerprinting like GCMS is a good technique compared to other fingerprinting like HPTLC using single or a few analytical marker/s. The combination of the results obtained by current pharmacopoeial tests and novel SFPTs would help in updating the current structure of monograph preparation of PHFs. Regulatory authorities may revise Pharmacopoeial tests for PHFs by incorporating SFPTs while bringing out regulation on standards for TMs.

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