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A DETAILED OVERVIEW OF VARIOUS TOOLS AND TECHNIQUES FOR THE DEVELOPMENT OF HERBAL MEDICINE

Baikuntha Adjuad*[1], Gunjan Kalyani[2], Kamlesh Kumar Dadsena[1]

[1]Govt. V.Y.T. PG Autonomous College, Durg, Chhattisgarh, India

[2]Shri Rawatpura Sarkar Institute of Pharmacy, Kumhari, Chhattisgarh, India.

*Corresponding Author: Email-baikunth1989@gmail.com

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ABSTRACT

As the demand and commercial value of the Herbal Medicines is increasing tremendously, there needs to be some standards for safety, quality and efficacy for medicinal plants and herbal products. In present era, there is a quick need systematic approach and well-designed methodologies for the standardization of herbal materials and formulations. Standardization methods should take into consideration. All aspects contributing to the quality of the herbal drugs should be taken in to consideration. Herbal Medicines are composed of many constituents.. Hence there needs to be reliable chromatographic fingerprinting which will represent pharmacologically active and chemically characteristic components. The information thus generated is potential for in the identification of an authentic drug, this exclused the adulterants thereby helping in the maintenenace of the quality and consistency of the drug. At present there are several analytical techniques for obtaining fingerprinting profiles of the herbal medicines. and these techniques are important tool for proving composition of herbal preparations. This helps in establishment of absolute criteria for uniformity. This paper deals with the various tools and techniques for the development of herbal medicine with advanced extraction, chromatographic techniques which further will lead to qualitative and quantitative evaluation of Herbal Medicines and formulations.. With the advancements in the analytical techniques there will develop a new era of development in the field of herbal research in order to materialize the quality standards and specifications in order to seek approval from regulatory authorities.

Keywords – Standardization, Herbal Medicine, Chromatographic fingerprinting, modification.

1. INTRODUCTION

Since ancient times the herbal drugs have been used for the treatment of a range of diseases. Medicinal plants plays key role in world health. There have been many advances in the field of herbal medicine in recent times, but still plants are an important factor for the health care system[1]. Thus the present era emphasizes in evolving a systematic approach so as to have a well-developed and designed methodologies for the standardization of herbal materials and formulations.

Traditional systems of medicine have been in use since ages. As per an estimate by WHO, 80 % of the world population depends on herbal products for their primary healthcare needs. The factors which have led to the re-emergence of the herbal medicine is the associated side effects and lack of proper medication for many chronic ailments[2].

The chemical constituents present in the medicinal plants are a part of their physiological functions and hence they have an appropriate and better compatibility with the human body when used in form of formulations[3].

Some of the multifactorial diseases like diabetes, cardiovascular diseases, cancer, and psychiatric disorders need therapeutic intervention at more than one level. Plants having the complex phytochemical mixtures are advantageous over single molecular entity in curing diseases. This will have an added advantage of being devoid of toxic side effects[2].

In view of commercialization of the herbal medicine assurance about safety, quality and efficacy of medicinal plants along with the herbal products are now an important issue to be addressed.. These herbal raw materials are prone to variation due to several factors, including the identity of the plants and seasonal variation (at the time of collection), the ecotypic, genotypic and chemotypic variations, drying and storage conditions and the presence of xenobiotics. World Health Organization (WHO) has stressed upon the importance of the qualitative and quantitative methods which will help in the characterization the samples, quantification of the biomarkers and/ or chemical markers and the fingerprint profiles. In view of the known principle active component the quantitation can easily be done of the compound. The active ingredients which contribute to the therapeutic efficacy is known, in that case the botanical preparations should be standardized to these compounds. In case the active ingredients are not yet known a marker substance specific for the botanical could be chosen for analytical purposes[4].

The advancements in modern techniques of analysis and the development in their application have made it easy and possible to overcome the difficulties arising in the standardization of these herbal plants and their formulations. Some of the prominent and important techniques like High-Performance Thin-layer Chromatography (HPTLC), Gas Chromatography (GC), Mass Spectrometry (MS), High-Performance Liquid Chromatography (HPLC), LC-MS, and GC-MS.

Initiating from sourcing of the raw material, standardization, preparation of the extracts, to the formulation of these extracts into suitable dosage form, the affecting factors vary with each plant species and part that is being used. The phytochemical needs to be generated and a strategy which is multiple-marker-based needs to be adopted in order to minimize the batch-to-batch variation which is essential to maintain quality, safety and efficacy[1]..

2. PHYTOCHEMICAL STANDARDIZATION

All the aspects that contribute to the quality of herbal drug needs to be taken in to consideration for methods of standardization. This is inclusive of the identity of the sample, organoleptic evaluation, pharmacognostic parameters, volatile matter, quantitative evaluation (ash values, extractive values), phytochemical evaluation, test for the presence of xenobiotics, microbial load testing, toxicity testing, and biological activity.

Of these, the phytochemical profile has special significance since it has a direct impact on the activity of the herbal drugs. The fingerprint profiles is the guideline to the phytochemical profile of the drug which is responsible for ensuring the quality, while quantification of the marker compound/s serves as an additional parameter while assessing the quality of the sample.

Phytochemical standardization encompasses very possible information generated with respect to the chemical constituents which are present in an herbal drug. Hence, the phytochemical evaluation for standardization purpose includes the following:

1. Preliminary testing for the presence of different chemical moities.
2. Quantification of the target chemical groups of interest (e.g., total alkaloids, total phenolics, total triterpenic acids, total tannins).
3. Establishment of fingerprinting profiles.
4. Multiple marker-based fingerprint profiles.
5. Quantification of important chemical constituents.

3. ADVANCES IN EXTRACTION OF HERBALS

a. Supercritical Fluid Extraction (SFE)

Technologically advanced extraction system involves use of gases, usually CO_2, and compressing them into a dense liquid. This liquid is then pumped through a cylinder which contains the material to be extracted. The extract-laden liquid is then pumped into a separation chamber from where the extract is separated from the gas after that the gas is recovered for re-use. Solvent properties of CO_2 can be manipulated and adjusted by varying the pressure and temperature. The advantages of SFE is its versatility that it offers in pinpointing the constituents to be extracted from the sample and the end product has virtually no solvent residues left in it (CO_2 gets evaporated). The demerit being that this technology is quite expensive..

Coupled SFE-SFC is the system in which a sample is extracted with a supercritical fluid. The extracted material is then placed in the inlet part of chromatographic system, thus the extract is directly chromatographed using supercritical fluid.

Coupled SFE-GC and SFE-LC is the system in which a sample is extracted using a supercritical fluid which is then depressurized in order to deposit the extracted material in the inlet part or a column of gas or liquid chromatographic system respectively. SFE is characterized by robustness of sample preparation, reliability, less time consuming, high yield and also has potential for coupling with number of chromatographic methods.

b. Microwave-Assisted Extraction (MAE)

Microwave-Assisted Processing (MAP) is advantageous over the conventional methods. The extraction of high-value compounds can be suitably be done from natural sources.MAE technology offers some combinational advantages which are as follows;

1. Improved products
2. Increased purity of extracts
3. Improved stability of marker compounds,
4. There is possibility to use less toxic solvents
5. Reduced processing cost
6. Increased recovery and purity of marker compound
7. Very fast extraction rates
8. Reduced energy and solvent usage.

.Recent advanced approaches could provide the additional spectral information, which will be very helpful for the qualitative analysis and even for the on-line structural elucidation such as hyphenated chromatography and spectrometry such as High Performance Liquid Chromatography–Diode Array Detection (HPLC–DAD), Gas Chromatography– Mass Spectroscopy (GC– MS), Capillary Electrophoresis-Diode Array Detection (CE-DAD), High-Performance Liquid Chromatography–Mass Spectroscopy (HPLC–MS) and High-Performance Liquid Chromatography– Nuclear Magnetic Resonance Spectroscopy (HPLC–NMR)[3].

4. ADVANCES IN CHROMATOGRAPHIC TECHNIQUES

1. Liquid Chromatography Preparative High Performance Liquid Chromatography

In Pharmaceutical industry, Liquid Chromatography - Mass Spectroscopy (LC-MS) has become method of choice in many stages of drug development due to advancement merits which includes electro spray, thermo spray, and ion spray ionization techniques offering high degree and detection of sensitivity and specificity [4].

Liquid Chromatography- Nuclear Magnetic Resonance (LCNMR)

The combination of chromatographic separation technique with NMR spectroscopy is another powerful advancement and further time saving method for the separation as well as structural elucidation of unknown compound and mixtures. It is very helpful for the

structure elucidation of light and oxygen sensitive substances. This technique allows the continuous registration of time changes as they appear in the chromatographic run automated data acquisition and processing in LC-NMR improves speed and sensitivity of detection[5-8].

5. FUTURE OF HERBAL DEVELOPMENT

The quality of the starting plant material, development, in-process controls, GMP controls, and process validation, and by specifications applied determines the quality of herbal substances, herbal preparations and herbal medicinal products throughout development and manufacturing process.

Specifications and acceptance criteria used to assure the quality of the herbal substances/preparations and herbal medicinal products at release and during the shelf life. The considerations listed above are necessary to ensure efficient production of herbal substances their preparations and herbal medicinal products of high quality. Thus the advanced analytical techniques like hyphenated chromatography and spectrometry will become very helpful for qualitative and quantitative analysis of herbal medicinal products which will minimize the batch to batch variation, which in turn will assure the safety, efficacy, quality and the acceptability of the herbal products.

6. CONCLUSION

For the scientific approval of herbal medicine, it is important to characterize the herbal drug. Thus this review briefly accounts for the application and analytical approach of tools and techniques having advanced features which plays a major role in screening and characterization of the phytoconstituents of herbal plants. This laids the foundation of herbal medicine to ensure the safety and efficacy of herbal drugs. With the development of technology and the current advancement in techniques for herbal medicines and novel approach towards research, the herbal industry is in shift of paradigm.. The developed high-technology oriented applications have given rise to intensive investigation with the involvement of the hyphenated techniques which serves as a rapid and unambiguous tool in the herbal research. This will benefit the entire pharmaceutical industry as well.

7. CONFLICT OF INTEREST

No conflict of interest.

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