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Phytoequivalence: A Balanced Perspective

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Abstract

Phytoequivalence is the term being used to deal with bioequivalence of a phytomedicine compared to another product that may be the subject of extensive research. In this concept, pharmaceutically equivalent drug products are formulated to contain the same amount of active ingradient in the same dosage form and to meet the same or compendia or other applicable standards i.e. strength, quality, purity and identity, but may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavours, preservatives), expiration time, and, within certain limits, labeling.

Origin of Concept

The concept of phytoequivalence was developed in Germany in mid 1990s, which means that one herbal extract matches, or is equivalent to, another herbal extract, more specifically, one of the clinically proven extracts [1]. Prof. Tylor [2] noted that the history of phytoequivalence in Germany was marked by previous versions of the German Pharmacopoeia (DAB) which specified exact conditions for plant preparations, including extraction methods, time and specific solvents. He outlined the scientific fact that ensuring safe and effective use of herbal remedies is directly linked with the performance of properly designed clinical trials leading to the introduction of new phytomedicines [2].

Why Phytoequivalence?

Several comparative clinical trials showed that phytopharmaceuticals had full therapeutic equivalence with chemotherapeutics and had the simultaneous advantage of being devoid of any adverse effects. The mechanism of action of herbal drugs and their extract preparations, which differ in many respects from that of synthetic drugs or mono substances, can be characterized as a polyvalent action and interpreted as additive or, in some cases, potentiating [3].

Phytoequivalence basically means chemical equivalence, in which, a chemical fingerprint profile of efficacy proven herbal product should be constructed which may serve as the reference for the quality control at commercial scale. Phytoequivalence is required due to following reasons:

(i) Each product has variation in active constituents.

(ii) To meet same compendia or other standards.

(iii) Extracts of similar drug should demonstrate similar pharmacological and physiological activity (the level of marker compound or derivatives may be considered).

(iv) It is necessary to match the products and doses in clinical trials.

(v) To achieve same efficacy in disease management.

The concept of phytoequivalence is in practice in order to ensure consistency in efficacy of herbal products. Depend on the concept of phytoequivalence, chromatographic fingerprint of herbal drugs is very useful for knowing the problem of analysis of herbal medicines. Several novel chemo-metric methods for evaluating the fingerprints of herbal products like fingerprint analysis by using HPLC–DAD, GC–MS, CEDAD, and LC–MS might be a powerful approach for analysis of herbal products [4,5].

Conclusion

Standardization based on a single or small number of chemical markers or classes of compounds serve to promote quality control and batch-to-batch consistency. A number of variables are important in the formulations of natural products like percentage of alcohol in a hydro-alcoholic men strum, extract concentration, uniformity of plant material, time and temperature of extraction

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etc. Phytomedicines must be compared and tested directly to synthetic drugs. Pharmaceutical companies should set aside 15 percent of gross sales revenues to research to research in areas of phytoequivalence. The need of the hour is to evolve a systematic approach and to develop well-designed methodologies for the standardization of herbal raw materials and herbal formulations.

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