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Abstract

Pre-Clinical and Clinical Study Rules for Herbal Medicines †

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Abstract: Herbal medicines consist of many different type of active ingredients obtained from medicinal plants. The amounts of compounds may be changeable with the environmental, harvesting, draying, storage conditions and process of production as well. In the therapy, efficacy, safety and quality are the main properties for both synthetic and natural medicines. Standardized extracts contain certain amount of active ingredient(s) without toxic impurities. Preventive, prophylactic, and curative activities of the standardized extracts are related with their variable chemical constitution. Because of many active ingredients within the herbal products, their toxicity assays, dose-response relationships and clinical trial tests are difficult to follow and not clear. In this review, the impotency of the pre-clinical studies on the herbal products, their standardization and trues/falses/challenges in their clinical trials will be investigated.

Keywords: herbal medicines; efficacy; safety; toxicity