

Design and Development of Herbal Formulations: Challenges and Solutions

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Abstract : As per the report of World Health Organization, more than 80% of world population uses medicines made from herbal and natural materials. They have stood the test of time for their safety, efficacy, cultural acceptability and lesser side effects. Quality assurance and control measures, such as national quality specification and standards for herbal materials, good manufacturing practices (GMP) for herbal medicines, labelling, and licensing schemes for manufacturing, imports and marketing, should be in place in every country where herbal medicines are regulated. These measures are vital for ensuring the safety and efficacy of herbal medicines. In the case of herbal products challenge begins at the stage of designing itself except the classical products. Selection of herbal ingredients, officinal parts to be used, proportions are vital. Once the formulation is designed one should take utmost care to produce the standardized product of assured quality and safety. Quality control measures should cover the validation of quality and identity of raw materials, in process control (as per SOP and GMP norms) and at the level of final product. Quality testing, safety and efficacy studies of the final product are required to ensure the safe and effective use of the herbal products in human beings. Medicinal plants being the materials of natural resource are subjected to great variation making it really difficult to fix quality standards especially in the case of polyherbal preparations. Manufacturing also needs modification according to the type of ingredients present. Hence, it becomes essential to develop Standard operative Procedure for a specific herbal product. Present paper throws a light on the challenges that are encountered during the design and development of herbal products.

Keywords : herbal product, challenges, quality, safety, efficacy

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