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Formulation of nutraceuticals and dietary supplements: Formulation and regulatory challenges

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The formulation of pharmaceutical quality dietary supplements that have adequate physical and chemical stability as well as are safe, cost effective and technologically feasible can entail numerous challenges. In contrast to drugs which are usually well defined chemical entities, botanicals are complex ingredients containing multiple chemical components and often several classes of compounds are present in a single product. Many of these compounds are unstable to heat, light, oxygen, alkaline pH and elevated humidity. They may also have poor flow, bulk density and variable particle size distribution. Thus successful development of nutraceuticals requires knowledge of the fundamental aspects of the physical and chemical properties of the various forms of the ingredients, the use of adequate techniques of manufacturing, selection of the right excipients and the addition of suitable manufacturing overages based upon critical stability studies. Regulatory requirements also pose challenges to the development of dietary supplements. Based on the ingredients and the claims, the formula can fit into different categories in different countries. Registration complexity and timing varies greatly by category and country with ever increasing scrutiny. In this oral presentation, I will talk about the formulation of dietary supplements and how it is similar and/or different from pharmaceutical formulations.

Biography

Shilpa Raut currently works at Nutrilite Health Institute (Amway) in the field of dietary supplement formulation where she is a part of the R&D group, involved in developing and bringing innovative science in the field of nutraceuticals. She completed her PhD in Pharmaceuticals and Drug Design from MCPHS University in 2013. She has also been an Instructor for Pharmaceutics I & II courses at MCPHS University. She has few publications in journals and several poster presentations to her credit. She was awarded the IPEC Graduate Student Scholarship Award for excellence in excipient research. She is also on the Editorial Board of *International Journal of Pharmaceutical Sciences: Open Access*.

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