

“Nutraceuticals 2020: Preparation and Evaluation of a Novel instant Drug Delivery System (iDDS) for Nutraceutical and Pharmaceutical Active Ingredients”

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The present work is related to the development and evaluation of a novel instant drug delivery system for the Active Ingredients that are used commonly in the nutraceutical and pharmaceutical preparations. This technology can be utilized for the availability of these active ingredients in-vivo much faster than the traditional particulate drug delivery systems. The preparation of these formulations involves the development of an innovative process for the conversion of active ingredient in a molecular form/nano dispersion in a suitable matrix which can be either presented in a final dosage form of tablets, capsules, dry syrups, suspensions etc. This novel active drug matrix has been named as ‘iAgglomerates’. The present delivery system ie iAgglomerates matrix can be used for diversified range of active ingredients which can help in significant clinical outcome of a nutraceutical or pharmaceutical product. Traditional nutraceuticals and cosmeceuticals hold pragmatic nature with respect to their definitions, claims, purposes and marketing strategies. Their definitions are not well established worldwide. They also have different regulatory definitions and registration regulatory processes in different parts of the world. Global prevalence of nutraceuticals and cosmeceuticals is noticeably high with large market share with minimal regulation compared to traditional drugs. The global market is flooded with nutraceuticals and cosmeceuticals claiming to be of natural origin and sold with a therapeutic claim by major online retail stores such as Amazon and eBay. Apart from the traditional formulations, many manufacturers and researchers use novel formulation technologies in nutraceutical and

cosmeceutical formulations for different reasons and objectives. Manufacturers tend to differentiate their products with novel formulations to increase market appeal and sales. On the other hand, researchers use novel strategies to enhance nutraceuticals and cosmeceuticals activity and safety.

The objective of this review is to assess the current patents and research adopting novel formulation strategies in nutraceuticals and cosmeceuticals. Patents and research papers investigating nutraceutical and cosmeceutical novel formulations were surveyed for the past 15 years. Various nanosystems and advanced biotechnology systems have been introduced to improve the therapeutic efficacy, safety and market appeal of nutraceuticals and cosmeceuticals, including liposomes, polymeric micelles, quantum dots, nanoparticles, and dendrimers. This review provides an overview of nutraceuticals and cosmeceuticals current technologies, highlighting their pros, cons, misconceptions, regulatory definitions and market. This review also aims in separating the science from fiction in the nutraceuticals and cosmeceuticals development, research and marketing.

The famous Hippocrates’ quote (400 BC), “Let food be thy medicine and medicine be thy food”, represents that there has been a great interest in herbal products since decades. There were many historical civilizations, such as ancient Egyptian, Greek, Roman and others that used herbal products and plants in treating and preventing diseases. The oldest written document that included different 12 recipes of herbal medications was discovered on Sumerian clay tablet in Nagpur (around 5000 years ago). Discords, the

father of pharmacognosy, wrote “De Materia Medica” book in 77 AD, which included 657 plant originated medicines. Hence, herbal products have been an interesting area along the human history.

There were many plants that were famous for their healing properties over the last millennia. For instance, ginseng had been used in China for treating and preventing different health problems [4]. Moreover, ancient Egyptians used many plants, including garlic, turmeric, thyme, cumin, juniper and others in medicine. Cinnamon represented a great value in both Roman and ancient Egyptian civilizations. The Indian culture also used natural products in treating and preventing several diseases, such as Ayurveda. Finally, honey was considered as one of the most well-known remedies in many ancient civilizations and was mentioned in religious books, such as the Holy Quran and Bible. These findings have triggered a series of studies in nutraceuticals field.

Fast dissolving oral films (FDOFs) are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improve the efficacy of APIs by dissolving within minute in oral cavity after the contact with less saliva as compared to fast dissolving tablets, without chewing and no need of water for administration. The FDOFs place as an alternative in the market due to the consumer’s preference for a fast-dissolving product over conventional tablets / capsules. The oral thin-film technology is still in the beginning stages and has bright future ahead because it fulfils all the need of patients. Eventually, film formulations having drug/s will be commercially launched using the oral film technology. However, for future growth point of view the oral thin film sector is well-positioned. In US market the OTC films of pain management and motion sickness are commercialized. More importantly, prescription OTFs have now been approved in US, EU and Japan which are the

three major regions. These approved Rx films, have potential to dominate over other oral dosage forms of the same drugs. It seems that the value of the overall oral thin film market will grow significantly. Self-emulsifying drug delivery systems (SEDDS) possess unparalleled potential in improving oral bio-availability of poorly water-soluble drugs. Following their oral administration, these systems rapidly disperse in gastrointestinal fluids, yielding micro- or nanoemulsions containing the solubilized drug. Owing to its miniscule globule size, the micro/nanoemulsified drug can easily be absorbed through lymphatic pathways, bypassing the hepatic first-pass effect. We present an exhaustive and updated account of numerous literature reports and patents on diverse types of self-emulsifying drug formulations, with emphasis on their formulation, characterization, and systematic optimization strategies. Recent advancements in various methodologies employed to characterize their globule size and shape, ability to encapsulate the drug, gastrointestinal and thermodynamic stability, rheological characteristics, and so forth, are discussed comprehensively to guide the formulator in preparing an effective and robust SEDDS formulation. Also, this exhaustive review offers an explicit discussion on vital applications of the SEDDS in bio-availability enhancement of various drugs, outlining an overview on myriad in vitro, in situ, and ex vivo techniques to assess the absorption and/ or permeation potential of drugs incorporated in the SEDDS in animal and cell line models, and the subsequent absorption pathways followed by them. In short, the current article furnishes an updated compilation of wide-ranging information on all the requisite vistas of the self-emulsifying formulations, thus paving the way for accelerated progress into the SEDDS application in pharmaceutical research.