

Solubility Enhancement of Poorly Soluble Drugs: A Design of Experiment Approach to Develop Nanosuspensions

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The poor aqueous solubility issues of drug molecules limit drug absorption through oral or dermal route and eventually, lower bioavailability due to hydrophobicity. Moreover, it is a big challenge to formulate poorly soluble drugs to increase solubility to obtain sufficient activity. Several new drug candidates, which are coming in regard to target-receptor geometry by high throughput screening, have high molecular mass and high Log P value that contributes to insolubility. According to Biopharmaceutical Classification System, the Class II and IV drugs consider as poorly soluble. Physical modifications (micronization, polymorph formation, solid dispersions, cyclodextrin complexes, use of organic solvent), chemical modifications (prodrug preparation, salt forms) or nanotechnological approaches (micelles, liposomes, nanoemulsions, etc.) are considered to overcome low water solubility problems. Physical and chemical modifications have several disadvantages such as not applicable to each drug active substance, not providing sufficient increased saturation solubility or causing loss of activity. In the last years, it is considered that drug nanosuspensions are one the most successful approaches to formulate poorly soluble compounds. Nanosuspensions are dispersed systems which have nanometer range, typically 200-600 nm, pure drug particles. They contain minimum amount of stabilizing agents such as surfactants and/or polymers. Nanosuspensions can be produced by precipitation, wet milling, high pressure homogenization, or combination of these methods. With unique properties of nanosuspensions by providing increased surface area of drug articles, they can improve saturation solubility and dissolution rate of poorly soluble drugs and hence oral or dermal bioavailability. The specific function of Quality by Design is known as Design of Experiment (DoE). The DoE approach statistically examines the interactions between variables within the design area and enables the development of formulations by taking into account the optimum product characteristics. DoE approach helps to develop nanosuspension formulation by reducing the number of experiments which brings cost and time saving.

Biography

Alptug Karakucuk was born in Turkey in 1988. He was graduated at Gazi University Faculty of Pharmacy in year 2012. He also took his Ph.D at Gazi University, Department of Pharmaceutical Technology in 2017 as a research and teaching assistant. He is still Ph.D., instructor at the same department. He is also co-founder and general manager of Fiber Pharma Drug, Cosmetics and Consulting Co. He published or presented several scientific studies in international areas, patented and commercialized some products, participated in scientific projects as researcher or coordinator.