American Journal of Drug Delivery and Therapeutics
ISSN 2349-7211
2020
Vol.7 No.5

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

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Abstract

The poor aqueous solubility issues of drug molecules limit drug absorption through oral or dermal route and evantually, lower bioavailability due to hydrophobicity. Moreover, it is a big challange 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, lipsomes, 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 spesific function of Qality 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., instructer 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.

Speaker Publications:

1. Alptug Karakucuk. (2020). In Vitro Caco-2 Cell Permeability Studies of Ziprasidone Hydrochloride Monohydrate Nanocrystals. Turkish Journal of Pharmaceutical Sciences, 10.4274/tjps.galenos.2020.67366.

2. Alptug Karakucuk (2020). Investigation of Formulation and Process Parameters of Wet Media Milling to Develop Etodolac Nanosuspensions. Pharmaceutical Research 37(6) 10.1007/s11095-020-02815-x .

3. Alptug Karakucuk., Ozoğul, C., & Acartürk, F. (2020). Screening of stabilizing agents to optimize flurbiprofen nanosuspensions using experimental design: Journal of Drug Delivery Science and Technology 57:101690.

4. Alptug Karakucuk, Acartürk, F. (2019). Optimization and in vitro evaluation of ziprasidone nanosuspensions produced by a top-down approach. Journal of Drug Delivery Science and Technology 52.

5. Alptug Karakucuk, S., Korkmaz, F. D., Acartürk, F., & Dilsiz, N. (2019). Evaluation of improved oral bioavailability of ritonavir nanosuspension. European Journal of Pharmaceutical Sciences 131.

23rd International Conference and Exhibition on Pharmaceutical Formulations ; Zurich, Switzerland- July 27-28, 2020.

Abstract Citation:

Alptug Karakucuk, Solubility Enhancement of Poorly Soluble Drugs: A Design of Experiment Approach to Develop Nanosuspensions, Formulations 2020, 23rd International Conference and Exhibition on Pharmaceutical Formulations; Zurich, Switzerland- July 27-28, 2020. (https://formulation.pharmaceuticalconferences.com/abstract/2020/solubility-enhancement-of-poorly-soluble-drugs-a-design-of-experiment-approach-to-develop-nanosuspensions)