

Optimization of finasteride nano-emulsion preparation by using chemometrics approaches (and/or Box-Behnken design and regression model)

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Background and Aims: Nanoemulsions (NEs) are very fine O/W dispersions, having droplets covering the size range of 100–600 nm. In pharmaceutical science they are used to drug delivery of poorly soluble drugs. Finasteride is a 5- α reductase inhibitor drug that nowadays is used orally to treatment of skin disorders such as acne, hirsutism and androgenic alopecia. The goal of this work is optimization of different variables of spontaneous N.E of Finasteride with high skin absorption and low systemic adverse effect.

Methods: Nano-emulsions were prepared using spontaneous emulsification method which occurs when an organic and an aqueous phase are mixed. The organic phase is a homogeneous solution of oil (or lipophylic drug), lipophylic surfactant and water-miscible solvent, and the aqueous phase consists of hydrophilic surfactant and water. The chemometric approach was applied for the optimization of N.Es' size. To optimize the size of droplets, the effect of three experimental parameters on size was investigated by mean of multivariate analysis. The considered Factors were sonication time (0-5min), span80 concentration (0-0.16g) and tween 80 concentration (0-0.26g).

Results: The experiments were performed according to Box-Behnken experimental design. The obtained regression model was characterized by both descriptive and predictive ability. The method was optimized with respect to average diameter as a response by following equation:

$129.547 + (-46.942 * st + 93.094 * tc - 755.836 * sc + 144.327 * st * sc - 134.5 * tc * sc + 101.968 * tc * tc + 474.383 * sc * sc)$

Conclusions: It can be concluded that the Box-Behnken experimental design provides a suitable means of optimizing and testing the robustness of Finasteride NE preparation method.

Keywords: Box-Behnken design; Optimization; Nanoemulsion.