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Preparation, Optimization and *in vitro* characterization of nanosuspension of Orlistat

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Background and Aims: Orlistat causes weight loss by lowering dietary fat absorption and it also improves lipid profiles, glucose control, and other metabolic markers. But because of high lipophilicity, low melting point and low chemical stability it's difficult to formulate the drug for receiving a maximum efficacy with the lowest side effects. In this study it has been tried to increase dissolution rate by using the nanosuspension method as a novel drug delivery system.
Method: Polyvinyl pyrolidone (PVP) as a polymer is used to stabilize the nanoparticles, and then spray drying has been done for obtaining the final dry product. Finally, the nanosuspension was characterized by differential scanning calorimetry (DSC), Transmission Electron Microscopy (TEM), scanning electron microscopy (SEM) atomic force microscopy (AFM), X-ray diffraction (XRD), and Fourier transform infrared spectrometry (FTIR). Also the drug dissolution rate in simulated intestinal fluid was compared with the conventional powder to characterize the in vitro efficacy of formulated orlistat.
Results: The results of optimization of several parameters showed that some parameters are most effective in preparation process. In optimization experiments the z-average of particle size of the optimized orlistat (ORL) nanosuspension was about 200±10 nm with good reproducibility and narrow size distribution with a PDI<0.2. In addition, the obtained SEM and TEM data support the AFM results showing cubic-like shaped nanostructures. The finally prepared nanosuspension showed higher dissolution rates in comparison to the reference product that could lead to decreasing the dose and dose dependent side effects.
Conclusions: Nanosuspension of ORL was formulated and spray-dried which showed acceptable dissolution rate and mean particle size around the 200± 10 nm. The yield of process was about 70%. Finally, the optimized nanosuspension of ORL was characterized *in vitro* with respect to dissolution rate, particle size, FTIR spectroscopy, TEM and SEM analysis.

Keywords: Orlistat; Nanosuspension; Nanotechnology