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Preparation, optimization and *in vitro* characterization of nanosuspension of cyclosporine

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Background and Aims: Department of Pharmaceutics School of Pharmacy, Zanjan University of Medical Sciences, Zanjan, IRAN Cyclosporine is widely used in prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants in conjucation with adrenal corticosteroid therapy. Cyclosporine may be used in patients previously treated with other immunosuppressive agent. The major problem of cyclosporine is poor solubility in water and at the same time in organic media. To solve these problems formulation of nanosuspensions is an attractive alternative.

Method: In the present study the different preparation parameters were optimized with respect to their corresponding effects on the particle size and polydispersity. Polyvinyl pyrolidone (PVP) was used as the stabilizer followed by the spray drying of the nanosuspension. 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 cyclosporine.

Results: Some parameters were most effective in preparation process. In optimization experiments the z-average of particle size of the optimized cyclosporine nanosuspension was about 250±15 nm with good reproducibility and narrow size distribution with a PDI<0.1. In addition, the obtained SEM and TEM data support the AFM results showing spherically 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 cyclosporine was formulated and spray-dried which showed acceptable dissolution rate and mean particle size around the 250± 15 nm. The yield of process was about 100%. Finally, the optimized nanosuspension of cyclosporine was characterized *in vitro* with respect to dissolution rate, particle size, FTIR spectroscopy, TEM and SEM analysis.

Keywords: cyclosporine, nanosuspension, nanotechnology.