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Preparation and characterization of simvastatin microcrystals by solvent change Methods: The effect of different surfactants

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Background and Aims: The present study was designed to study the effect of different surfactants as stabilizing agents on the physical properties and dissolution behavior of simvastatin microcrystals.
Methods: Simvastatin microcrystals were prepared by solvent change method from alcoholic solution. Aqueous solution containing different surfactants as stabilizing agents was prepared and poured rapidly into the drug solution under stirring. In the next step, the obtained dispersion was dried by freeze drying method. Different concentrations of anionic and non-ionic surfactants including sodium lauryl sulfate (SLS), Mirj 52, Pluronic F68 and Pluronic F127 were applied as stabilizing agents. Drug dissolution of all samples was studied and compared based on dissolution efficiency. Particles were also characterized by differential scanning calorimetry (DSC), x-ray diffraction (XRD), scanning electron microscopy (SEM) and particle size analyzer.
Results: The dissolution rate of simvastatin from all samples was increased significantly ($P < 0.05$) in comparison to the raw material. The best results obtained for the microcrystals prepared in the presence of Pluronic F68 (DE60 = 41.6 %) compared to the intact drug (DE60 = 4.9 %). Particle size of all samples was decreased apparently by this method. Based on XRD spectra, particles were crystalline in structure and no polymorphic change was occurred during sample preparation. DSC analysis also confirmed this result.
Conclusions: Simvastatin micronized powder was successfully prepared in the presence of different surfactants by solvent change method. The type of the surfactant could affect the drug crystal properties such as dissolution and particle size.

Keywords: Simvastatin; Microcrystals; Surfactants