Improvement of Drug Delivery Properties of Risperidone via Preparation of Oral Disintegration Tablet Containing Nanostructured Microparticles

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Abstract

Introduction: The aim of this study was to improve the dissolution profile of risperidone and increase the compliance of psychotic patients through the design of an oral disintegration tablet (ODT) of microparticles containing nanoparticles.

Methods and Results: In order to prepare nanoparticles, the effect of six surfactants on the size and stability of nanoparticles was evaluated. The nanoaggregate fabricated via the spray freeze drying (SFD) process using mannitol, lactose and maltodextrin as a matrix agent. Nine formulations were prepared and evaluated on the particle size, dissolution rate , and other physicochemical properties.Finally, the formulations of ODT were designed and evaluated.
The results show that using of cremophore EL and hydroxypropyl methyl cellulose E15 with the synergic effect can develop the risperidone nanosuspension with nano range particle size (~188 nm). Also, it is showed that fabrication of risperidone microparticles containig nanoparticles enhanced the drug dissolution up to 2 min for lactose-based microparticles (as a superior formulation) that is very faster time than coarse risperidone powder with dissolution time of 60 min. the formulations of ODT containing 10% Sodium Starch Glycolate and 88% Microcrystalline Cellulose as Super disintegrants were selected with a disintegration time of fewer than 30 seconds and dissolution time of 10 min in superior formulation.

Conclusions: It is indicated that the simultaneous use of non-ionic surfactants can prepare risperidone nanoparticles by creating a steric barrier around the drug particles. In addition, the dissolution rate of risperidone has increased significantly due to the small particle size of nanoparticles according to Noyes-Whitney equation. The use of sugars maintains the size of the nanoparticles and prevents the formation of irreversible coalescence of nanoparticles. Thus, this investigation shows that the preparation of microparticles containing nanoparticles using SFD is an easy and usable method for improving the dissolution profile of many low solubility drugs.

Key words: nanoparticles, dissolution, risperidone, oral disintegration tab.

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