Spray dried self-nanoemulsifying drug delivery systems for sertraline HCl pharmacokinetic study in healthy volunteers

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Abstract

Purpose: The aim of this study is to improvelow oral bioavailability of sertraline HCl by formulation
and characterization ofsolid self-nanoemulsifying drug delivery system [SNEDDS] using spray drying
technique.
Methods: Solubility of sertraline HCl in different vehicles was determined, and ternary phase
diagrams were constructed.Various formulations were prepared and characterized by morphological
characterization, differential scanning calorimetry and droplet size analysis. The formulations were
evaluated for in vitro release profi le in comparison to the marketed product [LustralÈ tablets]. The in
vivo study was performed on healthy human volunteers for pharmacokinetic analysis of the optimized
formulations.
Results: In vitro release data showed signifi cant improvement of dissolution rate of sertraline HCl
in form of liquid SNEDDS compared to the plain drug. Optimized liquid SNEDDS were chosen for the
preparation of solid SNEDDS by spray drying technique. High dissolution effi ciency values of solid
SNEDDS indicated the increase in dissolution characteristics of sertraline HCL in solid SNEDDS. F6
SNEDDS, comprising CapmulÈ 20%, CremophorÈ 53.4%, TranscutolÈ 26.6% showed highervalues for
AUC[0-72 h], AUC [0-Ð] and AUMC[0-72h] compared to LustralÈ tablets.
Conclusion: The prepared formulation reveals the potentiality of incorporating sertraline HCl in a
SNEDDS formulation to improve the biological performance of the drug.

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