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RESEARCH ARTICLE

Solubility enhancement of tizanidine by β-Cyclodextrin solid inclusion complexation technique

SUCHETA D. BHISE AND MILIN R. NAND

ABSTRACT

Tizanidine is a short-acting drug for the management of spasticity. Tizanidine is an agonist at α-2-adrenergic receptor sites and presumably reduces spasticity by increasing presynaptic inhibition of motor neurons. In animal models, tizanidine has no direct effect on skeletal muscle fibres or the neuromuscular junction, and no major effect on monosynaptic spinal reflexes. The effects of tizanidine are greatest on polysynaptic pathways. The overall effect of these actions is thought to reduce facilitation of spinal motor neurons. Its poor aqueoussolubility and slow dissolution rate of the drug lead to a lack of dose proportionality and high inter and intrasubject variability. The rationale of this study was to improve the biological performance of the drug by enhancingits solubility and dissolution through complexation with β-CD. In the present study attempt has beenmade to prepare and characterize inclusion complexes of Tizanidine with β-CD and evaluation of release kinetics of the dissolution of solid inclusion complex using different models. The phase solubilityanalysis indicated the formation of 1:1 molar inclusion complex of Tizanidine with β-CD. The apparentstability constant (KC) was 37.85 M^{-1} for β-CD. The inclusioncomplexes were prepared by three different methods *viz.*, Physical, Kneading and Co-precipitation method. Theprepared complexes were characterized using FT-IR, and Differential Scanning Colorimetry (DSC). The inclusioncomplex prepared with β-CD by Kneading method exhibited significant solubility enhancementand fastest dissolution.

Key words : β-CD Tizanidine, Kneading method, Inclusion complex, Phase solubility studies

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MEMBERS OF THE RESEARCH FORUM

Address for correspondence :
SUCHETA D. BHISE, Sinhgad Institute of Pharmaceutical Sciences, Lonavala, PUNE (M.S.) INDIA
Email : sdbhies.sips@sinhgad.edu

Coopted auhors :
MILIN R. NAND, Sinhgad Institute of Pharmaceutical Sciences, Lonavala, PUNE (M.S.) INDIA