Formulation Development and Biopharmaceutical Evaluation of Transdermal Therapeutic Systems

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Transdermal delivery is an important delivery route that delivers precise amounts of drug through the skin for systemic action. However, the applicability of transdermal delivery limited by several physical factors associated with the poor diffusion of large drug molecules across a resistant biological barrier. Considering the dosage requirements of various drugs, only less than 1 percent can be anticipated to be candidates for transdermal delivery. In order to obtain transdermal matrix patch containing fentanyl with excellent skin permeation, it has been formulated using various PSA and enhancer. The effects of these formulation factors on the drug release or the skin permeation of fentanyl were evaluated using Franz diffusion cells fitted with cuprophan membranes or excised guinea pig skins. Skin permeation rates of fentanyl from the matrix patches were increased by increasing drug concentration, PSA free volume and enhancer concentration, which may be due to changes in thermodynamic activity of the drug in the patch. Pharmacokinetic characteristics of the formulated fentanyl patch were evaluated using rabbits. All the pharmacokinetic parameters such as Cmax, Tmax, Css-av, Kel, and AUC were not significantly different between the fentanyl patch of this study and the reference.