

An open label study of modified matrix type TDDS of carvedilol & hydrochlorothiazide combination in healthy human volunteers

Agrawal S. S
India

Carvedilol (CRV) and hydrochlorothiazide (HCTZ) are the first line therapy for the treatment of uncomplicated essential hypertension. A major barrier to management of hypertension is the extent to which patient comply with the treatment regimen. The TDD system is unique and preferred system of delivery which provides nearly constant plasma level of medication over a prolonged period. Present study was designed to compare bioavailability, pharmacokinetic release profiles and adverse drug reaction along with phase I, open label, balanced, randomized, two- treatment, two- period, single- dose & crossover studies of CRV AND HCTZ containing modified transdermal patch with individual marketed oral formulation of same drugs in healthy, adult human subjects under fasting conditions. Pharmacokinetic parameters of patch were found to be C_{max} (45.127 ng/ml), T_{max} (36 h), and AUC (2183.045 ng h/ml) which signified that the modified patch showed higher concentrations, stable drug release and extent of drug absorbed from patch was greater than tablets. Post dose (after transdermal patches application) the marked decrease in blood pressure was recorded. Patch did not affect the biochemical profile of healthy subjects and showed no hypersensitivity during clinical trial, indicating safety in this regard. The results suggested that transdermal drug delivery system of carvedilol and hydrochlorothiazide showed better safety and efficacy than oral treatment for hypertensive patients.

agrawal_shyam@indiatimes.com