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Reversed phase-high performance liquid chromatographic method for the determination of etodolac in human plasma and bioequivalence studies

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Background and Aims:A sensitive and rapid Reversed-phase high-performance liquid chromatography method was developed for determination of a potent nonsteroidal anti-inflammatory and analgesic drug,etodolac in human plasma.
Methods: etodolac and ketorolac were usp reference standard. sample and standard solution preparation to a 100 Microliter aliquot of plasma,add 50 Micro liter of internal standard and 200 Micro liter of phosphate buffer and vortexed to mix.0.5 ml of isopentyl alcohol-hexan were added,shake for 15 minute,centrifuged at 1000 rpm for 5 minute,then 0.5 ml of glycine buffer 0.1 M was added, to the upper phase that was transferred to a clean tube, then 50 Micro liter of sample was injected to chromosorb Lc-7(ODS-10 Micrometer,250 mm x 4.6 mm stainless steel)that a mobile phase containing a mixture of phosphate buffer (pH 6.0)and acetonitrile (85:15 v/v) was pumped at a flow rate 1.8 ml/min with a UV detector setting at 226 nm and temperature of 50 °C for column.finally the linearity, precision ,accuracy , sensitivity and specificity of the method were evaluated.
Results: the study was done in a cross over design with healthy volunteers of average build, and younger than 35 years old. from the concentration in plasma-time data, the maximum concentration in plasma(Cmax),time t0, Cmax and area under the curve up to last measurable concentration (AUC0-t)or AUC0-infinity were calculated and compared by analysis of variance.with the exception of Cmax no significant differences between treatments were found in the rest of the parameters.the results indicate that the formulations of etodolac were bioequivalent with refrence product.
Conclusions: according to the peak concentration variation after etodolac administration ,it was needed to use the simple Rp-HPLC method for estimation of etodolac levels after administration in plasma that is sensitive, rapid, accurate, precise and can be use in quality control analysis.

Keywords: Bioequivalence studies; Etodolac; High performance liquid chromatography