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A comparative BA/BE study of conventional and sustained-release tablet formulations of aceclofenac in healthy male subjects

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Abstract

The purpose of this study is to examine bioequivalence of formulated aceclofenac sustained release tablets and a commercial brand of aceclofenac immediate release tablet. Matrix tablets of oral controlled release aceclofenac, using various viscosity grades of hydrophilic polymers and hydrophobic polymers were prepared and subjected to *in vitro* drug release studies.

An isocratic reversed phase high-performance liquid chromatographic (HPLC) method with ultraviolet detection at 281 nm has been developed for the determination of aceclofenac in dosage formulation. The intra- and inter-run precision and accuracy results were 99.07 to 100.20 with the %RSD of 0.45% and tailings factor 1.16. The proposed method was validated for its selectivity, linearity, accuracy, and precision.

For bioavailability studies, each of two groups of twelve fasting volunteers received either the reference standard or the test formulation (200 mg aceclofenac) orally once, using a cross-over design with a one week wash-out period. Their blood samples were obtained at regular time intervals over 24 h and analyzed by HPLC. Using the non- compartmental approach, pharmacokinetic parameters were determined and compared. It was found that the test aceclofenac sustained release formulation and the reference product were bioequivalent in greater extent.

Biography

B. B. Barik is a Professor in College of Pharmacy, Jazan University, Saudi Arabia. He received his PhD degree in Pharmacy, Pharmaceutics in 1993 from Jadavpur University, India. He was Professor in Utkal University, Bhubaneswar, India. His research interests are Novel Drug Delivery Systems, Micro- & Nano- particles, Pharmacokinetic Study etc. He has produced about hundred PG students and a dozen of PhD candidates. He has authored 50 research articles and presented about 100 papers. He received 5 Research Project Grants.