Biowaiver eligibility of a lower strength Ramipril/Hydrochlorothiazide immediate release tablets using a new validated HPLC analytical method. Drug Research

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Abstract
Bioequivalence studies are expensive, time consuming and invasive to humans. Accordingly, an alternative in vitro study (biowaivers) has been introduced for drugs which belong to BCS class I and III and for other strengths of already approved higher drug strength. The main objective of this study was to prove the biowaiver eligibility of a lower strength Ramipril/ Hydrochlorothiazide (2.5/12.5 mg) tablets. Visual and pharmacopoeial quality tests were performed on the higher and lower generic and on the reference listed drug to determine whether they are pharmaceutically equivalent. All products were investigated using the biowaiver criteria. Dissolution profiles were conducted at pH values 1.2, 4.5, and 6.8. Difference factor (f1) and similarity factor (f2) were calculated. The tested products were successfully complied with pharmacopeial requirements. f1was below 15 andf2was above 50 in all dissolution conditions. Precisely, Ramipril showed release higher than 85% within 15 minutes.f1andf2for Hydrochlorothiazide were 8 and 61 respectively at the recommended discriminative pH media.These results suggest that the current biowaiver criteria could be a sufficient guarantee of bioequivalence of the lower strength of Ramizide assuming that the product is manufactured at the same site and contains same quality and grade of excipients and in a proportional amounts.