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Biopharmaceutics classification system based studies to establish biowaiver status of levofloxacin brands

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This investigation has been conducted to evaluate the quality of tablets of a commonly prescribed flouroquinolone antibiotic, levofloxacin and to examine the possibility of biopharmaceutical classification system biowaiver. As levofloxacin is an important antibiotic used for treating the resistant bacterial infections and its several brands are available, their price fluctuations in the Pakistani community were analyzed and possibility of biopharmaceutical biowaiver on the popular branded tablets was also examined. For this purposes, ten (10) generic brands and the innovator brand were selected and compared their friability, hardness, disintegration and dissolution rates. *In vitro* testing showed less variation in their hardness and disintegration. The *in vitro* dissolution testing was carried out in three different media including 0.1 N HCl, pH 4.5 acetate buffer and pH 6.8 phosphate buffer and the samples were taken after every 5 min for up to 30 minutes. Ten (10) brands of levofloxacin (500 mg tablets) and six (6) dosage units of each brand were randomly selected for study. A total of about 1000 dissolution tests were performed and all the samples taken were analyzed by a validated UV spectrophotometer at 293 nm wave length. The dissolution test results obtained were recorded and graphs were prepared for the comparison. The dissolution data obtained revealed that though the brands of levofloxacin tablets manufactured in Pakistan have met the minimum pharmacopeial requirements but efforts are certainly further needed to get close to the innovator brand and to meet the requisite criteria for getting the biowavier status as different brands showed variable results in different dissolution media. It is conceivable that significance of the observed *in vitro* differences is still needed to be further evaluated and confirmed by *in vivo* bioequivalence studies.

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