Bioequivalence experimentation for generic's levofloxacin tablets 500 mg by using human urine

ABSTRACT

Bioequivalence experimentation had been investigated for generic's levofloxacin 500 mg with its innovator by using human urine. This experiment was done to analyze that either of generic and innovator product were equivalent. Experiment was carried out to 6 healthy men as volunteer and urine's sample were collected for 48 hours each product. Samples were analyzed by spectrofluorometric at 295 nm for excitation's wave length and 491 nm for its emission. On this method, ammonium molibdat was used to increase the intensity resulted by forming a chelate with the carbonyl and carboxylate oxygen of the levofloxacin. Buffer solution pH 3,5 was added and the volume was completed with methanol until 10 mL, both of them used as reagent because at that condition the intensity was better. Bioequivalence experimentation was done by comparing the value of bioavailability parameters, which are Du^{∞}, t^{∞}, and dDu/dt. Average value of Du^{∞} was about 429,1630 ± 28,8541 mg for generic's levofloxacin and about 464,5723 ± 21,6396 mg for innovator's one. Average t^{∞} was about 48,03 ± 0,39 hours for generic's product and 48,36 ± 0,71 hours for innovator's one. And for dDu/dt in this experiment was about 61,7470 ± 17,4078 mg/hours for generic's product and 64,2457 ± 22,6862 mg/hours for innovator's one. This result indicated that all 3 parameters not shown significant differences, it meant that both of levofloxacin was equivalent. The effectivity and quality of generic's product of levofloxacin was as good as the innovator's one.

Keywords : levofloxacin, spectrofluorometric, bioequivalence