

ABSTRACT

Bioequivalence Study of Ciprofloxacin Generic Tablet using Urinary Data

Ciprofloxacin is one of the antibiotic which has been widely used in Indonesia because of its broad spectrum activity against microorganism. Ciprofloxacin tablet in Indonesia available on innovator and generic product. There are different formulations of ciprofloxacin generic tablet and ciprofloxacin innovator tablet that cause differences in the bioavailability of these products which can also affect the drug levels in the blood. To ensure efficacy and safety of ciprofloxacin generic tablet, bioequivalence study is needed.

The aim of this study is to establish ciprofloxacin generic tablet bioequivalence compared with ciprofloxacin innovator tablet. Six healthy male volunteer participated to this bioequivalence study that designed to compare the bioavailability of ciprofloxacin generic tablet with ciprofloxacin innovator tablet. Urine samples were collected for 48 hours after dosing and ciprofloxacin concentration in urine assayed by spectrofluorometer.

Bioavailability parameters of ciprofloxacin were cumulative amount of ciprofloxacin excreted in urine (Du^{∞}) and maximum rate of ciprofloxacin excretion (dDu/dt_{max}). For generic tablet ciprofloxacin, the average value of Du^{∞} and dDu/dt_{max} were $314,32 \pm 23,90$ mg and $88,62 \pm 48,21$ mg/h and for innovator tablet of ciprofloxacin were $360,99 \pm 11,41$ mg and $92,86 \pm 51,31$ mg/h. Those data were analyzed using t-paired test method and showed significant difference for parameter Du^{∞} but did not show significant difference for dDu/dt_{max} parameter. In this study the relative bioavailability generic tablet ciprofloxacin ($87,44 \pm 8,5$ %) were within the acceptance range by BPOM, 80-125%. This result indicate that generic tablet of ciprofloxacin and the innovator tablet of ciprofloxacin are bioequivalent.

Keywords : Ciprofloxacin, generic, bioequivalence, spectrofluorometric, urinary data