

-  **Current Issue**
-  **Browse Issues**
-  **Search**
-  **About this Journal**
-  **Instruction to Authors**
-  **Online Submission**
-  **Subscription**
-  **Contact Us**
-  **RSS Feed**

Acta Medica Iranica

2009;47(4) : 15-21

A rapid and sensitive HPLC method for the analysis of metronidazole in human plasma: application to single dose pharmacokinetic and bioequivalence studies

Jaber Emami, Neda Ghassami, Hamed Hamishehkar

Abstract:

A sensitive, accurate and rapid reverse phase HPLC method was developed to quantitate plasma levels of metronidazole in order to conduct a comparative bioavailability studies. The drug and internal standard were added to plasma samples, vortexed and then zinc sulfate solution was added in order to precipitate the plasma proteins. Samples were centrifuged at 3000 rpm for 10 min. The supernatant layer was separated and analyzed on a phenyl (300 × 4.6mm) column, with 5% acetonitrile in 0.1 M KH₂PO₄ buffer (pH = 4.5) at 324 nm. The standard curve covering 0.15 – 30 µg/ml concentration range, was linear (r² = 0.9999), relative errors were within 2.48 to 9.15 % and the CV% ranged from 2.999 to 10.796. The method is suitable for bioavailability, pharmacokinetic, and bioequivalent studies in human. The in-vivo study was carried out in 12 healthy volunteers according to a single dose, two-sequence, cross over randomized design. The bioavailability was compared using the total area under the plasma level versus time curve (AUC₀₋₄₈, AUC_{0-∞}), peak plasma concentration (C_{max}) and time to C_{max} (T_{max}). No statistically significant difference was found between the AUC_{0-∞}, C_{max} and T_{max} values of the test and reference, Flagyl® (p > 0.05). The 90% CI for the ratio of the AUC_{0-∞} (0.94-1.07) and C_{max} (0.88-1.03) and the logarithmically transformed AUC_{0-∞} (0.99-1.01) and C_{max} (0.94-1.01) values of the generic product over those of Flagyl® was calculated to be within the acceptable limit of 0.80-1.20 and 0.80-1.25, respectively. It was, therefore, concluded that the generic metronidazole was bioequivalent with the innovator formulation.

TUMS ID: 2117

Full Text HTML  Full Text PDF  315 kB

top ▲

[Home](#) - [About](#) - [Contact Us](#)

TUMS E. Journals 2004-2009
Central Library & Documents Center
Tehran University of Medical Sciences

Best view with Internet Explorer 6 or Later at 1024*768 Resolutions