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# Bioequivalence study of seven amoxicillin capsule brands currently registered in Sudan

**[1]Osman B., [1]Idris B. El Tayeb, [2]H. A. Elsheikh and [1]Iman H. Abdoon**

[1]Department of Pharmacology, Faculty of Pharmacy University of Khartoum

[2]Department of Clinical Pharmacology, College of Medicine and Medical Sciences, Taif University, Saudi Arabia

A bioequivalence study was conducted in eight healthy volunteers to compare the bioavailability of seven amoxicillin capsule brands currently registered in Sudan. Those where Tauxil (Sigma-Tau, Sudan), Amoxicap (HO yan Hor Sdn Bhd, Malaysia), Penamox (Hikma, Jordan), Aramoxyl (ADMCO FZ, Syria), Lamoxy (Lyka, India), Maxil (Macter International, Pakistan) and Amoxidin (Lagab, Switzerland) as a reference standard product. 2x 250 mg capsules from each brand were administered as a single dose after an overnight fast with a washout period of seven days. Ten blood samples were collected over 8 h, amoxicillin concentrations in plasma were determined microbiologically by a cup-plate agar diffusion technique, and pharmacokinetic parameters were analyzed by assuming one compartment open model. Mean +/- SEM maximum concentration (Cmax), time to reach maximum concentration (Tmax), and area under the curve (AUC0-->t) were 5.57 +/- 0.39, 7.42 +/- 0.39, 7.4 +/- 0.344, 4.60 +/- 0.85, 5.74 +/- 0.35, 10.48 +/- 0.64, and 10.36 +/- 0.44 µg/ml, 107.46 +/- 2.68, 103.73 +/- 3.71, 98.1 +/- 110.83 +/- 2.35, 113.42 +/-87.23 +/-4.28 and 89.48 +/- 641 min, 1095.12 +/- 56.95, 1334.96 +/-54.2, 1528.03 +/- 33.32, 835.38 +/- 40.81, 1348.41 +/- 18.22, 1865.68+/- 106.52, and 1981.21 +/- 57.55 µg x min/ml for Tauxil, Amoxicap, Penamox, Aramoxyl, Lamoxy, Maxil, and Amoxidin, respectively. The percentage relative bioavailability of the investigated brands was found to be: Aramoxyl (42.2%), Tauxil (55.3%), Amoxicap (69.8%), Lamoxy (69.9%), Penamox (77.1), and Maxil (94.2%). Except for the brand Maxil, a statistically significant difference in Cmax and AUC was found between all brands and the reference standard product, Amoxidin. Similar difference was found in Tmax except for the brands Penamox and Maxil. The results indicate that with exception of the brand Maxil, all of the other brands can be considered inequivalent to the reference standard product Amoxidin with regard to the rate and extent of absorption under fasting conditions.

## Biography

Bashier Osman is a pharmacist and Lecturer in Pharmacology at the department of Pharmacology at Faculty of Pharmacy, University of Khartoum, Sudan, and he is ahead department of pharmacology since November 2011. His main research interests are bioequivalence and bioavailability of commercially available pharmaceuticals marketed in Sudan in addition to the clinical efficacy and safety of traditionally used Sudanese herbal medicines and the implications of complementary medicine use for pharmaceutical care.

Dr Osman obtained his first degree in Pharmacy and a master degree in Pharmacology at the Faculty of Pharmacy, University of Khartoum and holds a PhD from the University of Johann Wolfgang Goethe University Frankfurt.

His career has included employment as pharmacist at Community pharmacies in Sudan, and a medical representative for many pharmaceutical companies in Sudan.

dbashier@yahoo.com