Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **32** (6): 892-6 (2013)

Regular article
Received: April 21, 2013
Revised version: June 2, 2013
Accepted: June 3, 2013

Pharmacokinetics and Bioequivalence study of Nimesulide Tablets in Healthy Human Volunteers

Ya-Nan LI [1], Furong CUI [2], Haifeng WANG [3], Zhi LI [4], Min JI [5]*, & Shujaat A. KHAN [6]

[1] *Department of Neurosurgery Changhai Hospital Shanghai 200433*
[2] *Liaocheng People's Hospital, Liaocheng, Shandong, 252000, China*
[3] *Shanghai heng-rui pharmaceutical Co., Ltd., China*
[4] *Shanghai xuhai Bio Technology Co., Ltd., China*
[5] *Department of Pharmacy, Shanghai Antu Hospital, Shanghai, 200093, China*
[6] *Department of Pharmacy, COMSATS Institute of Information Technology, Abbottabad 22060, Pakistan.*

SUMMARY*. A comparative bioavailability study of two brands of nimesulide was carried out in 24 healthy human subjects according to a single dose, two sequences, and randomized cross-over design followed by the development of *in-vitro* and *in-vivo* correlation. Two oral formulations, Nims® as test and Nimaran® as reference were administered to each subject after an overnight fasting on two selected treatment days with a washout time period of 7 days. Blood samples were collected for a 12 h after dosing. Blood plasma was analyzed for nimesulide by sensitive, reproducible & accurate reverse phase HPLC method. The bioavailability was evaluated using parameters, peak plasma concentration (C_{max}), total area under plasma concentration (AUC0-∞), and time required to achieve peak plasma concentration (T_{max}). Their dissolution profiles were determined in 900 ml phosphate buffer (37 °C) using USP apparatus 2. The mean values of C_{max} and $AUC_{0-\infty}$ for Nimaran® were 4.094 ± 0.240 and 20.202 ± 1.066 μg.h/mL, respectively. While for Nims® these values were 4.0177 ± 0.279 and 20.891 ± 1.639 μg.h/mL, respectively. The T_{max} values of reference & test products were 2.167 ± 0.121 and 2.417 ± 0.149 h, respectively. Pharmacokinetics parameters were also calculated. The drug release from all the formulations was best fit to Higuchi's equation. The mechanism of drug release was diffusion along with erosion. A good linear correlation (R^2 = 0.9358 and 0.9206 for Nims® and Nimaran®, respectively) was obtained between the percent cumulative drug released and the percent cumulative drug absorbed data. The statistical inferences showed that Nims® is bioequivalent to Nimaran® and are comparable to those reported in literature and their dissolution is a good tool to predict their bioavailability.

KEY WORDS: Bioavailability, *In vitro-in vivo* correlation, Nimaran®, Nimesulide, Nims®, Pharmacokinetics.

* Author to whom correspondence should be addressed. *E-mail:* jiminjimin2000@126.com
Ya-nan Li and Fu-Rong Cui are the co-first author.

ISSN 0326-2383