

## Bioequivalence Evaluation of Two Brands of Meloxicam Tablets (Promotion<sup>®</sup> and Mobicox<sup>®</sup>): Pharmacokinetics in a Healthy Female Mexican Population

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**ABSTRACT:** We conducted a randomized, crossover study in 23 healthy young female volunteers to compare the bioavailability of two brands of meloxicam (7.5 mg) tablets and to obtain pharmacokinetic parameters of this molecule in Mexican population not reported previously. Two tablets (15 mg) were administered as a single dose on 2 treatment days separated by a 1-week washout period. After dosing, serial blood samples were collected for a period of 72 h. Plasma harvested was analyzed for meloxicam by a modified and validated high-performance liquid chromatography (HPLC) method previously reported. Pharmacokinetic parameters  $AUC_{0-t}$ ,  $AUC_{0-\infty}$ ,  $C_{max}$ ,  $T_{max}$ ,  $k_e$ , MRT and  $t_{1/2}$  were determined from plasma concentrations of both formulations, resulting in a  $C_{max}$  120% larger than and a  $T_{max}$  65% faster than those reported in other populations.  $AUC_{0-t}$ ,  $AUC_{0-\infty}$  and  $C_{max}$  were statistically tested for bioequivalence after log transformation data in a non-balanced design, and no significant differences were found either in 90% classical confidence interval (90% CI) or in Schuirmann test ( $p < 0.05$ ); thus, we concluded that bioequivalence existed between both formulations. Copyright © 2005 John Wiley & Sons, Ltd.

**Key words:** meloxicam; bioequivalence; pharmacokinetics; high-performance liquid chromatography (HPLC)

### Introduction

Meloxicam (MXC) (CAS 71125-38-7) (4-hydroxy-2-methyl-N-[5-methyl-2-thiazolyl]-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide) is a non-steroidal, anti-inflammatory drug (NSAID) that blunts prostaglandin synthesis selectively via type-2 cyclooxygenase (COX-2) inhibition, resulting in inflammation relief [1]. Thus, although the Food and Drug Administration (FDA) recognizes the use of MXC in osteoarthritis and rheumatoid

arthritis, its use in extra-articular diseases has been extended [2].

Oral or rectal doses of MXC are well-absorbed with absolute bioavailability of 90% [3]. There were no differences in bioavailability when MXC was administered under fasting conditions or following food intake; maximum plasma concentrations ( $C_{max}$ ) fluctuated from 1.5 to 1.7 µg/ml and reached 9–11 h ( $T_{max}$ ) after 30 mg was given orally [4]. MXC is bound to serum albumin at a high level (>99%) and readily penetrates into perivascular spaces, showing an apparent volume of distribution between 0.1 and 0.2 L/kg [5]. MXC is extensively metabolized in liver to four physiologically inactive metabolites that are excreted in both urine and faeces. CYP2C9 plays a major role in oxidative metabolism of MXC,

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