Comparison of the Pharmacokinetics of a Novel, Fast-Acting Oral Formulation of Meloxicam, MR-107A-02, versus Mobic® in Healthy Adult Human Subjects

Matthew A. Hummel[1], Andrew Shaw[1], Mark Shiyao Liu[1], Amarnath Jaiswal[2], Jeffrey P. Smith[3], Todd M. Bertoch[4]

[1]Viatris Inc., Global Clinical Pharmacology, Morgantown, WV, USA; [2]Viatris, Bioanalytical Lab, Telangana, India; [3]Viatris, Morgantown, WV, USA; [4]CenExel JBR, Salt Lake City, UT, USA

ASRA PAIN MEDICINE
51st Annual Regional Anesthesiology and Acute Pain Medicine Meeting
April 16-18, 2026 | Phoenix, Arizona

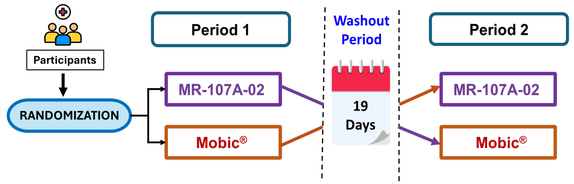
INTRODUCTION

A novel faster dissolving oral formulation of meloxicam, MR-107A-02, is being developed, to provide a rapid absorption, faster onset of action and safe and effective non-opioid analgesia in acute settings.

This study evaluated the safety, pharmacokinetics (PK) and bioequivalence of MR-107A-02, 15 mg tablets (Viatris) in comparison with Mobic®, 15 mg tablets (Boehringer Ingelheim, USA), under fasting conditions, in healthy adult human subjects.

METHODS

Figure 1: Study design



- Study design: Single-dose, randomized, two-period, crossover study (Fig.1).
- Participants: Healthy adult male subjects (n=18), aged 18-45 years, with normal body mass index between 19.0-24.9 kg/m^2.
- Pharmacokinetic assessments: Blood samples were collected pre-dose and post-dose at different time intervals. PK parameters analyzed were C_{max}, AUC_i, AUC_t, T_{max}, K_{el}, $t_{½}$, pAUC (0, 1, 2, 4 and 6-hours). They were evaluated by non-compartmental method using WinNonlin®.
- Statistical analysis: Geometric mean ratio (Test/Reference) and least-squares mean (ANOVA) with 90% confidence interval (CI) to compare PK parameters of 2 formulations.

RESULTS

Table 1: Summary meloxicam pharmacokinetic parameters

PK parameter	MR-107A-02 (Test) (N=16) [a]	Mobic® (Reference) (N=16) [a]
C_{max} (ng/mL)	2786.07 (20.04)	1611.14 (15.42)
AUC_t (ng/mL)*(hr)	49700.36 (32.44)	42834.54 (26.23)
AUC_i (ng/mL)*(hr)	55910.21 (44.27)	48233.47 (36.35)
$pAUC_{0-1}$ (ng/mL)*(hr)	1756.78 (22.87)	107.88 (88.61)
$pAUC_{0-2}$ (ng/mL)*(hr)	4154.71 (15.66)	630.59 (85.17)
$pAUC_{0-4}$ (ng/mL)*(hr)	8374.01 (14.21)	2854.53 (48.70)
$pAUC_{0-6}$ (ng/mL)*(hr)	11736.66 (14.33)	5607.48 (26.78)
K_{el} (1/hr)	0.04 (34.77)	0.04 (31.48)
$T_{½}$ (hr)	19.74 (37.65)	19.25 (34.55)
T_{max} (hr)^	0.75 (0.33 - 3.50)	4.00 (2.00 - 8.00)

Note: [a]Arithmetic mean (% coefficient of variation).
^Median (range)
Cmax, maximum observed plasma concentration; AUCt and AUCi, area under the plasma concentration versus time curve to the last measurable concentration and infinity, respectively; pAUC, partial area under the curve from time zero to time t; Tmax, time of maximum observed plasma concentration; K_{el}, elimination rate constant; $T_{1/2}$, apparent terminal elimination half-life.

- Of the 18 subjects enrolled, 16 subjects completed the study; 2 subjects discontinued. Mean (SD) age, 32 (6) years.
- The geometric mean ratio of C_{max} for MR-107A-02 vs. Mobic® was 171.74% (90% CI: 159.92-184.44).
- The CI was completely outside the bioequivalence range (80-125%), which indicated significantly higher availability of meloxicam in systemic circulation at an early phase for MR-107A-02 (Table 2).

Figure 2: Meloxicam mean plasma concentration–time curve over 72 hours

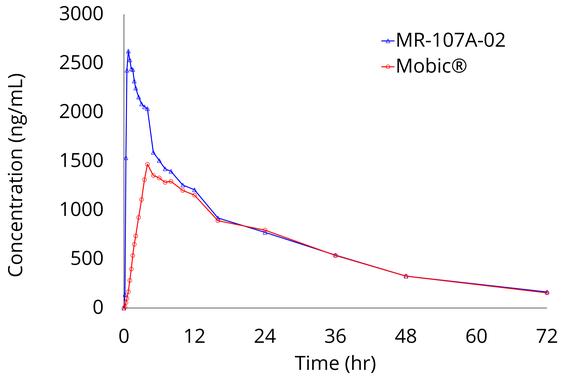


Figure 3: Meloxicam mean plasma concentration–time curve over 6 hours

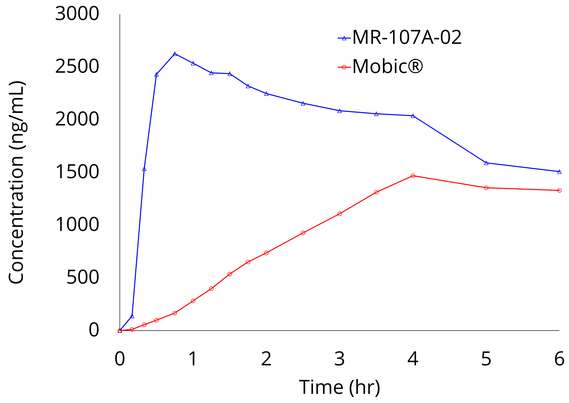


Table 2: Comparison of geometric mean of MR-107A-02 vs. Mobic® tablets

PK parameter	MR-107A-02 (Test) (N=16) [a]	Mobic® (Reference) (N=16) [a]	GMR (Test/Reference) (%)	90% Confidence Interval
C_{max} (ng/mL)	2734.34	1592.10	171.74	159.92-184.44
AUC_t (ng/mL)*(hr)	47442.14	41543.87	114.20	109.37-119.24
AUC_i (ng/mL)*(hr)	51878.35	45756.35	113.38	108.02-119.00
$pAUC_{0-1}$ (ng/mL)*(hr)	1710.42	75.50	2265.44	1587.74-3232.40
$pAUC_{0-2}$ (ng/mL)*(hr)	4103.96	406.80	1008.84	669.51-1520.15
$pAUC_{0-4}$ (ng/mL)*(hr)	8293.00	2486.70	333.49	266.30-417.64
$pAUC_{0-6}$ (ng/mL)*(hr)	11623.78	5401.74	215.19	190.99-242.44

Note: [a]acceptance criteria and outcome of bioequivalence result based on natural logarithm (Ln) transformed data for meloxicam. GMR. Geometric mean ratio

- MR-107A-02 demonstrated a rapid absorption compared with Mobic®, indicated by a higher C_{max}, higher partial AUCs, and a shorter T_{max}.
- No adverse events were reported in the study.

CONCLUSIONS

MR-107A-02 demonstrated a more rapid absorption than Mobic®, as evidenced by a higher C_{max}, higher early pAUCs and shorter T_{max} values whereas AUC_t and AUC_i remained essentially similar when administered under fasted conditions. These findings highlight the potential utility of oral MR-107A-02 formulation's fast-releasing design to be used in an acute pain setting.

Funding: This study was funded by Viatris.
Acknowledgement: This poster was designed by Mamatha. K from Viatris.
The study participants are acknowledged for their contribution in this study.