Clinical Study Synopsis for Public Disclosure

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Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobic®				
Name of active ingredient: UH-AC 62 XX, Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 19 Aug 2003	**Number:** U03-3238-01	**Study period (dates):** from 04 March 2003 to 25 April 2003		**Date of Revision** 10 Feb 2004

Title of study:	Bioequivalence study of UH-AC 62 XX tablets 10 mg (TF4) compared with the 10 mg capsule formulations following single peroral administration in healthy volunteers
Investigator:	[redacted]
Study center:	[redacted]
Publication (reference):	Data of this study has not been published
Clinical phase:	I
Objectives:	To investigate the bioequivalence of UH-AC 62 XX tablets 10 mg (TF4) and UH-AC 62 XX capsules 10 mg by single administration
Methodology:	Open-label, randomized, two-way crossover design
No. of subjects: **planned:** **actual:**	22 healthy male subjects entered: 22 enrolled: 22 entered: 22 Treatment Group A (UH-AC 62 XX; capsule → TF4): entered: 11 treated: 11 analyzed (for primary endpoint):11 Treatment Group B (UH-AC 62 XX; TF4 → capsule): entered: 11 treated: 11 analyzed (for primary endpoint):11
Diagnosis and main criteria for inclusion:	The healthy male volunteers who meet the following criteria; (1) Age ≥ 20 and ≤ 35 years (2) Weight : BMI ≥ 18.5 and < 25 (Weight (kg) / Height $(m)^2$) (3) Subjects who are judged by the investigator to be appropriate as the subjects of the study based on results of screening test (Table 9.3.1: 1) (4) Subjects who volunteer to participate and are able to fully understand and agree with this study by written informed consent
Test product: **dose:** **mode of admin.:** **batch no.:**	UH-AC 62 XX tablet 10 mg (TF4) 10 mg p.o., after at least 10 hours fast with 150 mL water 03001
Duration of treatment:	One day (single dose p.o.) for each treatment

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Reference therapy:	UH-AC 62 XX capsule 10 mg
dose:	10 mg
mode of admin.:	p.o., after at least 10 hours fast with 150 mL water
batch no.:	03002

Criteria for evaluation:

Pharmacokinetics:

Primary endpoints : C_{max}, $AUC_{0\text{-}60hr}$

Secondary endpoints : Plasma concentration profile and pharmacokinetic parameters (t_{max}, $t_{1/2}$, $AUC_{0\text{-}\infty}$, MRT_{po})

Safety:

Adverse events :
Adverse events were evaluated by physical examinations, laboratory tests and medical examinations

Statistical methods:

The pharmacokinetic parameters $AUC_{0\text{-}60hr}$ and C_{max} were log-transformed (natural logarithm) prior to fitting the ANOVA model. The difference between the expected means for log(Test)-log(Reference) were estimated by the difference in the corresponding Least Square Means (point estimate) and two-sided 90% confidence intervals based on the t-distribution will be computed. These quantities were back-transformed to the original scale to give the point and interval estimates for the expected median intra-subject ratio between response under test and response under reference. A claim of bioequivalence were made if the confidence intervals of $AUC_{0\text{-}60hr}$ and C_{max} for the drug formulations on the original scale are contained in the range of 80-125%.

SUMMARY – CONCLUSIONS:

Pharmacokinetics results:

The geometric mean ratio of the TF4 to the capsule in $AUC_{0\text{-}60hr}$ was 103.1%. The 90% confidence interval (CI) was from 100.1 to 106.1%. The geometric mean ratio of the TF4 to the capsule in C_{max} was 107.7%. The 90% CI was from 103.8 to 111.8%.

Safety results:

The safety profiles of both treatments were judged to be good. There was no clinically significant difference in safety profiles between the TF4 and the capsule.

Conclusions:

UH-AC 62 XX tablet 10 mg (TF4) and UH-AC 62 XX capsule 10 mg were proven to be bioequivalent.