Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country.

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

2. SYNOPSIS

Name of company: Boehringer Ingelheim International Trading (Shanghai) Co., Ltd.		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: **Mobic**				
Name of active ingredient: meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:** to		**Addendum No.:**
Report date: 01.2002	**Number:** U02-3112	**Study period (years):**		**2 months**

Title of study:	Relative bioavailability of 7.5 mg Mobic tablet manufactured in China in comparison with 7.5 mg tablet manufactured in Germany after a single oral dose in Chinese healthy volunteers. Open, randomized, two-way cross-over trial.
Investigator:	[redacted]
Study centre(s):	1
Publication (reference):	
Clinical phase:	I
Objectives:	The objective of this study is to compare the pharmacokinetic parameters of the 7.5 mg Mobic tablet manufactured in China with the 7.5 mg Mobic tablet manufactured in Germany.
Methodology:	2-way cross-over, randomized, open
No. of subjects entered:	
total:	20
each treatment:	20
Diagnosis and main criteria for inclusion:	Healthy male subjects
Test product:	Mobic tablet manufactured in China
dose:	7.5 mg /tablet£¬ 2 tablets Qd
mode of admin.:	oral
batch no.:	20000902
Duration of treatment:	Single administration
Reference therapy:	Mobic tablet manufactured in Germany
dose:	7.5 mg /tablet£¬ 2 tablets Qd
mode of admin.:	oral
batch no.:	908096

Name of company: Boehringer Ingelheim International Trading (Shanghai) Co., Ltd.		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobic		**SUPPLEMENTARY SHEET**		
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume: I**	**Page:**	**to**	**Addendum No.:**
Report date: 01.2002	**Number:** U02-3112	**Study period (years):**		2 months

Criteria for evaluation:

Efficacy: C_{max}£¬ $AUC_{0-\infty}$,£¬t_{max}, $t_{1/2}$£¬λ£¬CL/f£¬Vd/f£¬MRT, AUC_{0-t}

Safety: Pulse rate, Systolic and diastolic blood pressure, Laboratory values,Adverse events,Global assessment of tolerability by investigator

Statistical methods: Descriptive statistics including geometric mean 90% confidence intervals for pharmacokinetic parameters

SUMMARY - CONCLUSIONS:

Efficacy results:

The PK parameters of the test tablets were as follows: AUC_{0-n} = 52.85(±12.18) h·μg/ml, AUC_{0-inf}=57.90(±14.03) h·μg/ml, C_{max}=1.493(±0.338) μg/ml, Tmax=5.65(±3.17) h, and $T_{1/2}$=26.29(±4.37) h; the PK parameters of reference one were as follows: AUC_{0-n} = 57.10(±15.55) h·μg/ml, AUC_{0-inf} = 63.98(±19.94)h·μg/ml, C_{max}=1.682(±0.399)μg/ml, T_{max} = 4.60(±1.82)h and $T_{1/2}$ = 28.03(±6.75)h. There were no statistical differences ($p>0.05$) in the main PK parameters of two types of meloxicam tablets (AUC_{0-n}, AUC_{0-inf}, C_{max}, T_{max} and $T_{1/2}$) analyzed by ANOVA. The relative bioavailability of the meloxicam tablets produced by Shanghai Boehringer Ingelheim Pharmaceutical Co. Ltd. was 94.46% (±14.60%, n=20) compared with the Mobic produced by Boehringer Ingelheim International Company, Germany.

Safety results:

No adverse events (AE) and serious adverse events (SAE) were reported in all of the volunteers during this test.

Conclusions:

AUC_{0-n} and AUC_{0-inf} of the test and reference tablets using logarithmic transformation were statistically evaluated by two-one side test. It showed that two preparations were bioequivalence.