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***.

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Micardis				
Name of active ingredient: Telmisartan		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 07 JUL 2003	**Number:** U03-3191	**Study period (dates):** 19 July 2002 to 10 August 2002		

Title of study:	Bioequivalence study of BIBR 277 tablet (Erythritol based) compared with its capsule formulation in healthy male volunteers.
Investigator:	[redacted]
Study center(s):	[redacted] Japan
Publication (reference):	Not yet published
Clinical phase:	I
Objectives:	To investigate the bioequivalence of BIBR 277 tablet(Erythritol based) vs. BIBR 277 capsule
Methodology:	open-label, randomised, two-way crossover design
No. of subjects:	
planned:	randomised: 30
actual:	enrolled: 58 randomised: 30
Diagnosis and main criteria for inclusion:	Healthy male volunteers who meet the following criteria; Age $\geq$ 20 and $\leq$ 35 years Weight : BMI $\geq$ 17.6 and $\leq$ 26.4 (Weight (kg) / Height $(m)^2$) Subjects who are judged by the investigator to be appropriate as the subjects of the study based on results of screening test (Table 3. 2. 1) Subjects who volunteer to participate and are able to fully understand and agree with this study by written informed consent
Test product:	BIBR 277 tablet (Erythritol based)
dose:	20mg
mode of admin.:	Oral administration with 150 mL water after at least 10 hrs fast
batch no.:	02080
Duration of treatment:	One day (single dose p.o.) for each treatment
Reference therapy:	BIBR 277 capsule
dose:	20mg
mode of admin.:	Oral administration after at least 10 hrs fast with 150 mL water

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batch no.:	02081
Criteria for evaluation:	
Pharmacokinetics:	primary endpoints: C_{max} and $AUC_{0\text{-}72\ hr}$
	secondary endpoints: individual time courses of the Telmisartan plasma concentrations, t_{max}, $t_{1/2}$, $AUC_{0\text{-}\infty}$ and $MRT_{0\text{-}\infty}$
Safety:	Clinical examination including physical examination, vital signs, ECG; laboratory tests and adverse events
Statistical methods:	The pharmacokinetic parameters C_{max} and $AUC_{0\text{-}72hr}$ are log transformed (natural logarithm) prior to fitting the ANOVA model. The difference between the expected means for log(Test)-log(Reference) is estimated by the difference in the corresponding Least Square Means (point estimate) and two-sided 90% confidence intervals based on the t-distribution are computed. These quantities are then 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 is made if the confidence intervals of C_{max} and $AUC_{0\text{-}72hr}$ for the drug formulations on the original scale are contained in the range of 80-125%.
SUMMARY – CONCLUSIONS:	
Efficacy results:	The ratios of gmean values of C_{max} and $AUC_{0\text{-}72hr}$ of tablet to those of the capsule were 108.2% and 107.7%, respectively. The 90% CIs were 97.7 - 119.9% for C_{max} and 100.6 - 115.2% for $AUC_{0\text{-}72hr}$. Both were included in BE range.
Safety results:	There was no clinically significant difference in safety profiles after single administration between the tablet and the capsule. The tablet (Erythritol based) has no matter in terms of safety compared with the capsule.
Conclusions:	The 90% CI of the geometric means of both ratios C_{max} and $AUC_{0\text{-}72hr}$ were included in the BE acceptance range (80 - 125%), and therefore the capsule and the test tablet of 20 mg BIBR 277 were proven to be bioequivalent.
	There were no clinical subjective and objective symptoms during the study. There was no clinical abnormality related to the investigational products in the physiologic and medical examination. Single administration of BIBR 277 tablet (Erythritol based) had no matter in terms of safety.