Lotus

CLINICAL STUDY REPORT 400/04

TITLE

A RANDOMIZED, OPEN LABEL, TWO TREATMENT, TWO PERIOD, TWO SEQUENCE, REPEATED DOSE, CROSSOVER, BIOEQUIVALENCE STUDY OF TAMSULOSIN HYDROCHLORIDE MR 0.4 MG CAPSULES OF CIPLA LIMITED, INDIA AND OMNIC® 0.4 MG CAPSULES OF YAMANOUCHI, GERMANY, IN HEALTHY ADULT MALE HUMAN SUBJECTS, UNDER FED CONDITIONS.

Test Drug A	:	Tamsulosin Hydrochloride MR 0.4 mg capsule manufactured by Cipla Ltd, India
Reference Drug B	:	Omnic® (Tamsulosin Hydrochloride) 0.4 mg retard capsule manufactured by Yamanouchi, Germany
Sponsor	:	Cipla Limited, India
Protocol identification date:		July 06, 2004
Study Initiation date	:	September 16, 2004
Clinical study start date	:	September 22, 2004
Clinical study completion date:		October 17, 2004
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Date of report : November 22, 2004

2.0 SYNOPSIS

Name of Sponsor/Company:	Cipla Limited, India
Name of Finished Test Product:	Tamsulosin Hydrochloride MR 0.4 mg capsule
Name of Active Ingredient:	Tamsulosin
Title of Study:	A randomized, open label, two treatment, two period, two sequence, repeated dose, crossover, bioequivalence study of Tamsulosin Hydrochloride MR 0.4 mg capsules of Cipla Limited, India and Omnic® 0.4 mg capsules of Yamanouchi, Germany, in healthy adult male human subjects, under fed conditions.
Clinical study start date:	September 22, 2004
Clinical study completion date:	October 17, 2004
Objective:	To assess the bioequivalence at steady state of Tamsulosin Hydrochloride MR 0.4 mg capsules of Cipla Ltd, India with Omnic® 0.4 mg capsules of Yamanouchi, Germany, in healthy adult male human subjects, under fed conditions, after repeated doses.
Number of Subjects:	30 healthy human adult subjects were enrolled in the study and 29 subjects completed the study.
Main Criteria for Inclusion:	Healthy human adult subjects aged 18 – 45 years who voluntarily consented to participate in the trial.
Test Drug A: Batch No: Dose and Mode of Administration:	Tamsulosin Hydrochloride MR 0.4 mg capsule manufactured by Cipla Ltd, India E40111 Single oral dose administered with 240 ml of water daily for seven consecutive days.
Reference Drug B: Batch No: Dose and Mode of Administration	Omnic® (Tamsulosin Hydrochloride) 0.4 mg Retard capsule manufactured by Yamanouchi, Germany 04F10/41 Single oral dose administered with 240 ml of water daily for seven consecutive days.

Criteria For Evaluation:	C_{max}, $AUC_{0-\tau}$ (=AUC_{0-24}), T_{max} , C_{min}, $t_{½}$ and % fluctuation on day 7 were evaluated. The standards for bioequivalence applied were: ➢ The 90% confidence interval of the relative mean C_{max}, $AUC_{0-\tau}$ of the Test and Reference product had to be between 80% and 125% for log-transformed data. ➢ The 90% confidence interval of the relative mean ratio for C_{min} of the test and reference product should be between 75 % and 133 % for log-transformed data.
Statistical Methods:	Statistical analysis was performed on the pharmacokinetic data for 29 subjects using the SAS ® software for Windows, release 8.2, (SAS Institute Inc., Cary NC, USA). Statistical methods of measures of central tendency, dispersion and analysis of variance (Generalized Linear Model –GLM) were employed. The 90% confidence intervals for Tamsulosin log-transformed Parameters C_{min}, C_{max} and $AUC_{0-\tau}$ were 83.80 % to 108.79 % (Ratio= 95.48 %), 94.54 % to 116.69 % (Ratio= 105.03 %) and 87.56 % to 108.06 % (Ratio= 97.27 %), respectively.
SUMMARY CONCLUSION:	Based on the results obtained in this study, the Tamsulosin Hydrochloride MR 0.4 mg capsules of Cipla Limited, India and Omnic® 0.4 mg capsules of Yamanouchi, Germany, are bioequivalent at steady state under fed conditions.
Date of the Report:	November 22, 2004