CONFERENCE ABSTRACT

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COMPARATIVE STUDY OF EXTENDED RELEASE ANTIHYPERTENSIVE DRUG BIOEQUIVALENCE AMONG HEALTHY HUMAN VOLUNTEER

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ABSTRACT

Diltiazem is a benzothiazepine derivative which works by relaxing the smooth muscle in the walls of arteries, resulting in opening and allowing blood to flow more easily. This study was performed by using diltiazem extended release two capsules of test formulations or a one of the reference formulation for comparing in-vivo characteristics. The formulation so used was expected to be bioequivalent, tablets of each formulation were dissolved in four different buffer media. Healthy male volunteers were administered with 360 mg diltiazem after keeping in fasting condition for ten hour period in a randomized, open label, three period crossover design. A validated LC-MS/MS method was used to analyze the plasma samples collected after subsequent period of 72 hours. The adverse events occurred during the period was studied under safety profile and tolerability of formulations. At the end of the study it was found that the test and reference products meets the criteria for bioequivalence. Diltiazem is a narrow therapeutic index drug and exhibits dose-dependent pharmacokinetics. Both the test product follow the limits prescribed for bioequivalence of narrow therapeutics index drugs ,80 to 120 %.The forms of the drug were shown to have similar trends in half-life despite the difference in absorption rate.

KEYWORDS: Diltiazem, bioequivalence, diltiazem, bioavailability, antihypertensive.

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