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TITLE

CLINICAL STUDY OF THE BIOEQUIVALENCE OF TRIMETAZIDINE IMMEDIATE RELEASE AND MODIFIED RELEASE TABLETS

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Trimetazidine is an anti-ischemic metabolic agent, which improves myocardial glucose utilization through inhibition of fatty acid metabolism. Modified release (MR) Trimetazidine was developed to maintain effective plasma concentrations. The present study was conducted with the aim of determining the bioequivalence of two different pharmaceutical formulations of trimetazidin, immediate (IR) and modified release (MR) tablets.

A bioequivalence trial was performed in 24 and 36 healthy male volunteers with the aim of comparing a new generic product (tablets containing Triemtazidin (20 mg, IR), (35 mg, MR) with the original product. The trial was performed according to an open, cross-over design in one study centre. In each of the two study periods (separated by a wash-out of 7 days) a single dose of one tablet (test or reference) was administered. Blood samples were taken up to 48 and 72 h post dose for IR and MR tablets respectively, the plasma was separated and the concentrations of Trimetazidin were determined by a liquid chromatography-Mass spectrometry method with a quantification limit of 2.5 ng/ml. $AUC_{0\text{-infinity}}$ $AUC_{O\text{-tlast}}$ C_{max} and t_{max} were calculated for both formulations.

The parametric 90 % confidence intervals for the primary target parameters were used. In the case of oral administration of trimetazidine, C_{max} and other parameters were found to be within the bioequivalence acceptance range. This means that these IR and MR tablets of trimetazidine can be used interchangeable.