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Bioequivalence and pharmacokinetic comparison between extended release capsules of carvedilol phosphate 40 mg: An open label, balanced, randomized-sequence, single-dose, two-period crossover study in healthy male volunteers

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An open-labeled, balanced, single-dose, two treatment, two period, two sequence, randomized two way crossover study was conducted in 18 healthy adult male subjects to determine the pharmacokinetic, bioavailability and bioequivalence of carvedilol phosphate 40 mg extended release capsules in comparison with Coreg CR™ extended release capsules after single dose administration under fed conditions with a wash-out period of at least 7 days was used. Each volunteer received a 40 mg capsule of the reference (or) test drug, respectively. On the day of dosing, blood samples were collected before dosing (at 0.0 hr) and 0.50, 1.00, 1.50, 2.00, 2.50, 3.00, 3.50, 4.00, 4.50, 5.00, 5.50, 6.00, 6.50, 7.00, 7.50, 8.00, 10.00, 12.00, 16.00, 24.00, 36.00 and 48.00 hours after dosing. Analysis of carvedilol and its metabolite 4-hydroxy phenyl carvedilol concentrations was performed using a validated LC-MS/MS method. The pharmacokinetic parameters were analyzed using the non-compartmental model. Drug safety and tolerability were assessed. The primary pharmacokinetic parameters at 90% CI were within the 80 to 125% interval required for bioequivalence as stipulated in the current regulations of the USFDA acceptance criteria. The geometric mean ratios (Test/Reference) between the two products of extended-release carvedilol capsule under fed condition were 114.41% (93.68%-116.74%) and 113.15% (96.67%-122.45%) for C_{max} ratios, 101.54% (95.73-104.85%) and 102.72%(95.12%-113.35%) for AUC0-t ratios and 104.56% (103.24%-107.58%) and 105.73% (95.45%-110.50%) for AUC0-inf ratios of carvedilol and its metabolite 4-hydroxy phenyl carvedilol respectively. 18 volunteers had completed both treatments. There was no significant difference of the Tmax parameter between the two formulations ($p>0.05$). No serious adverse events related to the study drugs were found. This single dose study found that the test formulation carvedilol phosphate ER capsules is bioequivalent in terms of rate and extent of absorption to the reference formulation Coreg CR™ ER capsules of 40 mg under fed condition in healthy adult male volunteers according to the USFDA regulatory guidance.

Biography

S Raghunadha Reddy has completed his PhD from Jawaharlal Nehru Technological University, Anantapur and currently doing Postdoctoral studies from Department of Pharmaceutical Science, School of Pharmacy, University of Maryland. Previously he was worked as Head of Quality Assurance and Regulatory Affairs at Clinsync Clinical Research Pvt. Ltd. He has published 17 papers in reputed journals and has been serving as an Editorial Board Member of *Journal of Comprehencive Pharmacy*. He has extensive experience in Good Clinical Practice-ICH, Good Laboratory Practice, QMS (ISO9001-2008), Bioanalytical method Development and validation, Computer System Validations (21 CFR Part-11) and Regulatory Affairs.

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