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Title: Bioequivalence comparison between two different formulations of alverine citrate 120mg capsules: 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, 2-treatment, 2-period, 2-sequence, randomized crossover study was designed and conducted to determine the pharmacokinetic, bioavailability and bioequivalence of alverine citrate 120 mg capsules in comparison with Spasmonal Forte® 120 mg capsules after single dose administration under fasting conditions in 12 healthy adult male subjects. Each volunteer received a 120 mg capsule of the reference(or)test drug respectively. On the day of dosing, blood samples were collected before dosing & at various time points up to 4 days after dosing. Analysis of alverine and its metabolite 4-hydroxy alverine concentrations was performed using a validated LC-MS/MS method. The pharmacokinetic parameters were analyzed using the non-compartmental model. 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 EU acceptance criteria. The geometric mean ratios (Test/Reference) between the two products of alverine capsule under fasting condition were 111.15% (98.67%-122.4%) and 113.41% (94.68%-118.74%) for C_{max} ratios, 112.72% (91.12-114.35%) and 104.54% (94.73%-103.85%) for AUC_{0-t} ratios and 103.73% (94.45%-111.5%) and 104.56% (103.24%-107.58%) for AUC_{0-inf} ratios of alverine and its metabolite respectively. 12 volunteers had completed both treatments. There was no significant difference of the T_{max} parameter between the two formulations (p >0.05). Drug safety and tolerability were assessed. No serious adverse events related to the study drugs were found. This single dose study found that the test formulation alverine citrate capsules is bioequivalent to the reference formulation Spasmonal Forte® capsules of 120 mg under fasting condition in healthy adult male volunteers according to the EU regulatory guidance.

Biography

S Raghunadha Reddy has completed his PhD at the age of 30 years 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 Comprehensive 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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