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Glycerophosphate does not interact with components of parenteral nutrition

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The primary objective of this study was to determine and compare the pharmacokinetic (PK) profiles of inorganic phosphate in the serum after continuous administration of pure glycerophosphate and glycerophosphate contained in total parenteral nutrition (TPN) emulsions. This approach was selected to identify potential PK interactions between TPN components and glycerophosphate. The serum PK profile of inorganic phosphate after continuous intravenous administration of a sodium glycerophosphate containing TPN emulsion was determined in ten healthy, white (5 male/ 5 female) volunteers. A pure sodium glycerophosphate formulation served as reference (R). Standard criteria of bioequivalence were applied. Subjects were enrolled in the double-blinded study and were randomly allocated to receive the test (T) and R preparations on two occasions in a 2-sequence crossover study design. The volunteers received ⅓ of the maximum recommended body weight (BW) adjusted intravenous daily dosage (13.3 ml/kg BW) of the T drug over a period of 8 h. The amount of total phosphate (0.101 mmol/kg) and duration of administration were identical for the T and R drugs. Study days were separated by wash-out periods of at least 88 h. Serum concentrations of total inorganic phosphate were measured serially over a 36-h period using a validated method. A statistical mixed analysis of variance (ANOVA), based on population averages was used for testing bioequivalence between these study preparations. The 90% confidence intervals (90% CIs) of inorganic phosphate in serum were calculated for the T/R ratios of the area under the time–concentration curve from time zero to 36 h (AUC_{0-36}), the maximum concentration (C_{max}) and the concentration 5 min before the end of infusion (C_{ss}) for a bioequivalence range from 0.80–1.25. The mean T/R ratios fell completely within the 90% CIs with values of 1.016 (CI: 1.005–1.028), 1.013 (CI: 0.981–1.047) and 0.932 (CI: 0.886–0.980) for AUC_{0-36}, C_{max} and C_{ss}, respectively. In total, 3 mild adverse events in the R group were detected after starting intravenous infusion, while no adverse events were observed in the T group after treatment. Primary pharmacokinetic parameters were within the defined bioequivalence range of 0.8-1.25. Thus, inorganic phosphate levels were essentially similar between the two investigational medicinal products tested in the present study. These findings confirm the concept that nutritional components of the T drug do not significantly interact with glycerophosphate. The two study preparations proved to be safe during the investigation.