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Acarbose bioequivalence: Exploration of new pharmacodynamic parameters

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To investigate bioequivalence (BE) testing of an acarbose formulation in healthy Chinese volunteers through the use of recommended and innovative pharmacodynamic (PD) parameters. Following the Food and Drug Administration (FDA) guidance, a randomized, cross-over study of acarbose test (T) and reference (R) (Glucobay®) formulations was performed with a 1-week wash-out period. Preliminary pilot studies showed that the appropriate dose of acarbose was 2×50 mg, and the required number of subjects was 40. Serum glucose concentrations after sucrose administration (baseline) and co-administration of sucrose/acarbose on the following day were both determined. Three newly defined PD measures of glucose fluctuation (glucose excursion (GE), GE' (glucose excursion without the effect of the homeostatic glucose control), and fAUC (degree of fluctuation of serum glucose based on AUC)), the plateau glucose concentration (C_{ss}), and time of maximum reduction in glucose concentration (T_{max}) were tested in the evaluation. The adequacy of the two parameters recommended by the FDA, $\Delta C(SG,_{max})$ (maximum reduction in serum glucose concentration) and AUEC(0-4h) (reduction in the AUC(0-4h) of glucose between baseline and acarbose formulation) was also evaluated. The T_{max} values were comparable, and the 90% confidence intervals of the geometric test/reference ratios (T/R) for $\Delta C(SG,max)$, C_{ss}, GE, and fAUC were all within 80-125%. The parameter GE' was slightly outside the limits, and the parameter AUEC(0-4h) could not be computed due to the presence of negative values. In acarbose BE evaluation, while the recommended parameter $\Delta C(SG_{max})$ is valuable, the combination of C_{ss} and one of the newly defined glucose fluctuation parameters, GE, GE', and fAUC is preferable than AUEC(0-4h). The acarbose test formulation can be initially considered to be bioequivalent to Glucobay®.

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