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Consistency evaluation of the nifedipine oral formulations

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Abstract

The consistence evaluation of oral solid preparation, as The Twelfth-five National Drug Safety Control Planning, will be activated since 2013, and thousands of generic drugs will be tested or evaluated by Pharmaceutical Company itself or by the drug inspection institutes assigned by SFDA. Nifedipine is a dihydropyridine calcium channel blocker, and its main uses are as an antianginal and antihypertensive. Dozens of nifedipine sustained release-tablets, named as generic drugs, come into the market, and need to be evaluated. Nifedipine sustained release-tablets from different Pharmaceutical Companies were selected in this study, and the crystal polymorphs, preparation dissolution, contents and bioequivalence were investigated. The crystal polymorphs of nifedipine was analyzed by X-ray powder diffraction and differential thermal analysis, a single-dose, randomized-sequence and 3-period crossover of bioequivalence study was conducted, and nifedipine contents of tablets and concentration in plasma were determined by HPLC-MS method. The peak location and intensity of nifedipine characteristics were significant difference and polymorphic between preparations, The dissolution and contents all meets China Pharmacopoeia but with some differences. The main pharmacokinetic parameters of tested A, B and C nifedipine preparations were as follows: t1/2, (6.696 }2.219), (9.631 }8.119) and (5.59 }1.19)h; Tmax, (2.80 }0.50), (2.70 }0.47) and (1.71 } 1.07) h; Cmax, (76.69 }19.51), (75.558 }17.601) and (264.76 }83.75) ng.mL-1; AUC0-36, (534.128 } 159.944), (526.682 } 154.862) and (1253.46 }592.75)ng.mL-1.h; AUC0-∞, (551.682 }174.344), (610.83 } 353.90) and (1266.34 }601.93) ng.mL-1.h. It could be concluded that the big difference of absorbed extent of nifedipine sustained release-tablets existed, which might be introduced by nifedipine crystal polymorphs or through pharmaceutical technology, and resulted in clinical un-bioequivalence.

Biography

Prof. Guo Ruichen, Ph.D. tutor and the director of the Institute of Clinical Pharmacology, Qilu Hospital of Shandong University, was graduated from Pharmacy Faculty of Shandong University in 1982, and completed his advanced study at Institute of Clinical Pharmacology, Bern University of Switzerland from May.1991 to Sept. 1993. Guo is mainly engaged in PK, BA, BE, metabonomics, TDM, etc. More than 200 tests of different categories new drugs in human have been conducted, 170 scientifi c papers published both home and abroad and 70 master or doctor degreestudents were or will be graduated, till Nov. 2012.