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药物代谢清除率体外预测模型研究进展与问题分析

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摘要:

本文介绍了药物代谢清除率临床前预测的相关理论和数学模型,从而将所得的体外代谢清除率数据用于肝清除率的 推算,并根据国内外学者对该预测方法准确度评估及体内体外相关性考察,指出该研究领域中出现的难点和可能的 改进方案;以期使体内代谢行为的预测更加准确,并对尽早确定创新药物在人体内药物代谢动力学行为是否适合进 行进一步研究开发具有重要的指导意义,并为今后创新药物的研发提供新的思路。

关键词: 代谢清除率 药物代谢动力学 体内-体外相关性

Advances and related issues in the use of *in vitro*methods to predict metabolic clearance rate of new drugs

ZHANG Qian; WANG Guang-ji

### Abstract:

The reasonable prediction of metabolic clearance rate from the humanized in vitrosystem is valuable in drug discovery, which is commonly used in the identification and optimization of compounds that mostly like to process appropriate pharmacokinetic characteristics in humans. A detailed development of the general theory and models underlying the prediction of in vivohepatic drug metabolism from in vitrodata I 王广基 were presented. Furthermore, the accuracy when extrapolating from in vitrodata considering the in vitroin vivo correlation, method-logical issues and potential solutions were discussed as well. This review can give us a better insight into exploring methods whereby human clearance can be accurately predicted from in vitrodata in the process of new drug development.

Keywords: pharmacokinetics in vitro-in vivo correlation metabolic clearance rate

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