

论文

地非三唑的RP-HPLC法测定及其体外代谢研究

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摘要:

目的为研究抗早孕新药地非三唑(DL111-IT)的代谢作用机理和进一步开发利用,建立其体外代谢的RP-HPLC测定法。方法以Lichrospher ODS-C₁₈为色谱柱,甲醇-pH 7.5磷酸盐缓冲液(70:30)为流动相,检测波长:235 nm,流速1.0 mL·min⁻¹,地西洋为内标,对鼠肝微粒体孵育液中DL111-IT的RP-HPLC法进行方法学研究。应用建立的方法对DL111-IT在不同来源的鼠肝微粒体中的体外代谢进行试验。结果DL111-IT浓度在1.01~101.0 μg·mL⁻¹呈良好的线性关系,在不同浓度下测得平均绝对回收率和相对回收率分别为(92±4)%和(100.3±1.9)% (N=5);DL111-IT在鼠肝微粒体中的代谢,β-萘黄酮组明显快于其他组。结论本法简便、准确,可用于DL111-IT的体外代谢研究。

关键词: 地非三唑 高效液相色谱 药物代谢 肝微粒体

RP-HPLC DETERMINATION OF DIPHENYTRIAZOL IN RAT LIVER MICROSOMAL INCUBATES AND ITS APPLICATION IN *in vitro* METABOLISM

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Abstract:

AIMTo establish a RP-HPLC method for determination of diphenytriazol (DL111-IT) in rat hepatic microsomes. METHODS DL111-IT in rat hepatic microsomal incubates was extracted with chloroform, using diazepam as internal standard. The determination was performed on a Lichrospher ODS-C₁₈ reversed column (25 cm×0.46 cm ID) with mobile phase of methanol-pH 7.5 phosphate buffer (70:30) at a flow-rate of 1.0 mL·min⁻¹. A UV-VIS detector was operated at 235 nm.RESULTSThe assay was linear from 1.01~101.0 μg·mL⁻¹ for DL111-IT. The limit of detection was 0.15 μg·mL⁻¹ (signal-to-noise ratio 3) and the limit of quantification was 1.01 μg·mL⁻¹ (RSD<10%, N=4). The method afforded average recoveries of (100.3±1.9)% (N=5), and intra-day and inter-day RSD were less than 5.0% (N=5). The method allowed study of the *in vitro* phase I metabolism of DL111-IT in rat liver microsomal incubates. The microsomes induced by β-naphthoflavone showed high enzymatic activity for DL111-IT phase I metabolism. CONCLUSIONThe method is simple, accurate and can be used to study the metabolism of DL111-IT in rat hepatic microsomes.

Keywords: HPLC drug metabolism hepatic microsomes diphenytriazol

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