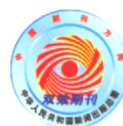


中国药学会系列期刊/《CAJ-CD》规范执行优秀期刊/美国《化学文摘》荷兰SCOPUS等国际著名检索系统收录  
中国中文核心期刊 中国科技核心期刊 中国科学引文数据库来源期刊

CHINESE JOURNAL OF NEW DRUGS

# 中国新药杂志<sup>®</sup>

ISSN 1003-3734  
CN 11-2850/R  
CODEN ZXZHA6



14  
2012  
Vol.21 | No.14

美国FDA对药物临床试验的监管

单克隆抗体类药物组织交叉反应常见问题的探讨

生物样品分析中基质效应和准确度的确定

双波长梯度洗脱高效液相色谱法测定冲和软膏中芍药苷和蛇床子素的含量

药品不良反应信号发现及验证研究方法概述

Z H O N G G U O X I N Y A O Z A Z H I

ISSN 1003-3734



# 目次

半月刊 1992年创刊  
第21卷第14期 2012年7月30日出版

- 1571 •世界新药之窗•  
•新药述评•
- 1573 首个治疗疼痛和发热的静脉注射产品布洛芬静脉注射液……………李健和, 胡焰, 谢双, 等  
•新药研发论坛•
- 1578 美国FDA对药物临床试验的监管……………陈永法, 黄丽
- 1583 从WHO最新技术报告看WHO基本药物遴选调整进展……………文小静  
•新药申报与审评技术•
- 1587 中日肌肉刺激性试验的比较研究及探讨……………金毅, 王晓炜, 王平  
•重大新药创制专项巡礼•
- 1591 盐酸伊立替康脂质体临床前药代动力学、耐受性和药效学研究……………郑庆梅, 韩景宾, 官新江, 等
- 1596 正丁醇萃取技术制备高纯度栀子苷的工艺研究……………丁越, 张彤, 陶建生, 等  
•生物医药前沿•
- 1600 单克隆抗体类药物组织交叉反应常见问题的探讨……………林志, 屈哲, 吕建军, 等
- 1603 重组人生长激素在健康猕猴体内的比较药代动力学……………欧伦, 王清清, 孙效, 等  
•综述•
- 1607 生物样品分析中基质效应和准确度的确定……………韩南银, 徐秉玖
- 1611 顶端钠依赖性胆酸转运体及其抑制剂的研究进展……………刘洪涛, 何红伟, 王菊仙, 等
- 1616 小分子趋化因子受体4拮抗剂研究进展……………高立娜, 杨晓虹, 巩宏伟, 等
- 1621 神经血管单元信号通路机制研究进展……………张宁, 李韶菁, 余红, 等
- 1627 磷脂分子在水中形成不同聚集体的机制探讨……………薛士兴, 王向涛, 李永吉  
•临床研究•
- 1633 复方苦参注射液联合化疗对晚期肺癌患者免疫功能和癌胚抗原的影响……………洪永贵, 黄涛, 王俊生
- 1636 帕利哌酮缓释片门诊治疗精神分裂症疗效及社会功能的临床研究……………任海婴, 李荔
- 1639 帕利哌酮缓释片与氯氮平治疗难治性精神分裂症对照研究……………刘美玲, 刘晓军, 张乃敏
- 1643 钆典凝胶系统微创治疗癫痫的临床效果及对心理因素的影响……………赵慧峰, 金珊珊, 任莉
- 1647 国产与进口度洛西汀治疗抑郁症的临床疗效与安全性比较……………王来海, 张瑞岭, 马金芳, 等
- 1651 埃克替尼治疗17例晚期肺癌非吸烟患者的早期临床疗效观察……………孙婧华, 张阳, 赵金波, 等
- 1654 体外高频热疗联合吉西他滨治疗晚期复治型胆系肿瘤的疗效……………张克勤, 魏红梅, 陆月香
- 1658 普瑞巴林治疗咖啡因依赖1例……………温金峰, 张延赤, 宁连才  
•实验研究•
- 1660 真菌PHF-9化学成分及其抗肿瘤活性研究……………王翠翠, 刘明, 魏鉴腾, 等
- 1665 大苞鸢尾种子的化学成分研究……………林彬彬, 王国凯, 郑媛媛, 等
- 1668 质谱技术分析联合用药抗大鼠肝纤维化的作用……………廖明, 莫财锋, 周怡, 等
- 1672 高效液相色谱法测定蝙蝠葛碱的平衡溶解度和油水分配系数……………高秀蓉, 蒋学华, 王婷
- 1676 双波长梯度洗脱高效液相色谱法测定冲和软膏中芍药苷和蛇床子素的含量……………孙士真, 王亚静, 张德芹, 等
- 1681 米非司酮固体分散体的制备及性质研究……………陈凯, 段雪艳, 刘颖, 等
- 1686 参葛颗粒中挥发油成分的提取及其包合工艺研究……………骆慧琳, 谢燕, 邹珊珊, 等  
•药师与临床•
- 1690 对1例重症肺炎患者的药学监护……………龙锐, 朱深银, 邱峰, 等  
•不良反应•
- 1694 药品不良反应信号发现及验证研究方法概述……………王盼, 朱文涛
- 1698 深圳地区中药制剂不良反应报告分析……………聂小忠

# CONTENTS

CHINESE JOURNAL OF NEW DRUGS

Semimonthly  
Volume 21, Number 14  
July 30, 2012

- 1573 The first intravenous ibuprofen product for the treatment of pain and fever  
1578 FDA's administration of drug clinical trials  
1583 Progress in the selection strategy of essential medicines by WHO reflected by the latest WHO technical reports  
1587 Comparison and discussion of muscular irritation test methods between China and Japan  
1591 Preclinical pharmacokinetics, tolerance and efficacy of irinotecan hydrochloride liposomes  
1596 Study of preparation process for high purity of Geniposide by extraction technology with butanol  
1600 Investigation of common issues in cross-reactivity test of monoclonal antibody drugs  
1603 Comparison pharmacokinetics of recombinant human growth hormone in healthy rheuses  
1607 Determination of the matrix effect and accuracy in the analysis of biological samples  
1611 Advances in studies on apical sodium-dependent bile acid transporter and its inhibitors  
1616 Research advance of small molecule CCR4 antagonists  
1621 Advance in research of signal pathways of neurovascular unit  
1627 Discussion on mechanism of the formation of different phospholipid molecules aggregates in water  
1633 Effect of Compound kushen injection combined with chemotherapy on immune function and CEA in advanced lung adenocarcinoma  
1636 Clinical study on the efficacy of paliperidone extended-release tablets in the treatment of schizophrenia outpatients and its effect on social function  
1639 A comparative study on efficacy and safety of paliperidone extended-release tablets and clozapine in treatment of resistant schizophrenia  
1643 Clinical effect of Carisolv for the treatment of dental caries and its impact on the mental  
1647 Comparison of the clinical efficacy and safety of domestic duloxetine with imported duloxetine in treating depression  
1651 Clinical efficacy of icotinib in treatment of seventeen non-smokers with advanced lung adenocarcinoma  
1654 Efficacy of high-frequency hyperthermia combined with gemcitabine for treatment of advanced recurrent biliary tract cancer  
1658 A case of pregabalin for the treatment of caffeine dependence  
1660 Chemical metabolites from fungus PHF-9 and their anti-tumor activity  
1665 Study on chemical constituents of the seeds of *Iris bungei* Maxim.  
1668 Analysis of differentially expressed proteins in liver tissue of rats with liver fibrosis after combination therapy by SELDI-TOF-MS  
1672 Determination of equilibrium solubility and oil/water partition coefficient of dauricine by HPLC  
1676 Simultaneous determination of peoniflorin and osthole in Chonghe ointment by HPLC with gradient elution and dual wavelength detection  
1681 Studies on preparation and dissolution of mifepristone solid dispersion  
1686 Study on the extraction of volatile oil in Shenge granules and the preparation of their  $\beta$ -CD inclusion compounds  
1690 Pharmaceutical care for one patient with severe pneumonia  
1694 An overview of the methods of signal detection and validation for adverse drug reaction  
1698 Analysis of adverse drug reactions associated with Traditional Chinese Medicine preparation reported in Shenzhen
- LI Jian-he, HU Yan, XIE Shuang, *et al*  
CHEN Yong-fa, HUANG Li  
WEN Xiao-jing  
JIN Yi, WANG Xiao-wei, WANG Ping  
ZHENG Qing-mei, HAN Jing-bin, GONG Xin-jiang, *et al*  
DING Yue, ZHANG Tong, TAO Jian-sheng, *et al*  
LIN Zhi, QU Zhe, LÜ Jian-jun, *et al*  
OU Lun, WANG Qing-qing, SUN Xiao, *et al*  
HAN Nan-yin, XU Bing-jiu  
LIU Hong-tao, HE Hong-wei, WANG Ju-xian, *et al*  
GAO Li-na, YANG Xiao-hong, GONG Hong-wei, *et al*  
ZHANG Ning, LI Shao-jing, YU Hong, *et al*  
XUE Shi-xing, WANG Xiang-tao, LI Yong-ji  
HONG Yong-gui, HUANG Tao, WANG Jun-sheng  
REN Hai-ying, LI Li  
LIU Mei-ling, LIU Xiao-jun, ZHANG Nai-min  
ZHAO Hui-feng, JIN Shan-shan, REN Li  
WANG Lai-hai, ZHANG Rui-ling, MA Jin-fang, *et al*  
SUN Jing-hua, ZHANG Yang, ZHAO Jin-bo, *et al*  
ZHANG Ke-qin, WEI Hong-mei, LU Yue-xiang  
WEN Jin-feng, ZHANG Yan-chi, NING Lian-cai  
WANG Cui-cui, LIU Ming, WEI Jian-teng, *et al*  
LIN Bin-bin, WANG Guo-kai, ZHENG Yuan-yuan, *et al*  
LIAO Ming, MO Cai-feng, ZHOU Yi, *et al*  
GAO Xiu-rong, JIANG Xue-hua, WANG Ting  
SUN Shi-zhen, WANG Ya-jing, ZHANG De-qin, *et al*  
CHEN Kai, DUAN Xue-yan, LIU Ying, *et al*  
LUO Hui-lin, XIE Yan, ZOU Shan-shan, *et al*  
LONG Rui, ZHU Shen-yin, QIU Feng, *et al*  
WANG Pan, ZHU Wen-tao  
NIE Xiao-zhong

**Directed by:** State Food and Drug Administration  
**Sponsored by:** China Medical Science Press  
China National Pharmaceutical Group Corp.  
Chinese Pharmaceutical Association  
**Editor-in-Chief:** SANG Guo-wei  
**Board Chairman:** SHI Sheng-yi  
**Director:** SHI Sheng-yi SONG Rui-lin WU Shao-zhen LI Shao-li  
DENG Jin-dong ZHU Jing-jin FENG Lan  
**Board of Directors Secretary:** ZHOU Ying  
**General Manager:** FENG Lan  
**Deputy General Manager:** LIU Da-wei  
**Deputy Editorial Department Director:** YANG Qing  
**Chief Marketing Officer:** HAO De-zhi  
**Editor and Publisher:** Chinese Journal of New Drugs Co., Ltd.

**Address:** Floor 8, Lunyang Building, No.6 Beisanhuanzhonglu  
Xicheng District, Beijing 100120, China  
**Tel:** (010)82282302 / 82282300 / 82282301 / 82282329 / 82282309 / 82282326  
**Fax:** (010)82282289  
**Website:** <http://www.newdrug.cn>  
**E-mail:** [cnj2009@gmail.com](mailto:cnj2009@gmail.com)  
**Printer:** Beijing Jinqihao Printing Co., Ltd.  
**Domestic Distribution:** Beijing Post Offices  
**Overseas Distribution:** China International Book Trading Corp.  
(P.O.Box 399 Beijing, China)  
**Domestic Subscription:** Local Post Offices  
**Periodical Registration:** ISSN 1003-3734 CN 11-2850/R  
**Publication Date:** July 30, 2012  
**Copyright:** 2012 by Chinese Journal of New Drugs Co., Ltd.