

刊名题写: 桑国卫

主管单位: 国家食品药品监督管理局

主办单位: 中国医药科技出版社

中国医药集团总公司

中国药学会

主 编: 桑国卫

董事长/总经理: 宋瑞霖

董 事: 宋瑞霖 吴少祯

李少丽 邓金栋 朱京津

副总经理: 冯 岚 王 喆

编辑部主任: 韩 培

编辑出版: 《中国新药杂志》有限公司

地 址: 北京市西城区北三环中路乙6号

伦洋大厦8层

邮政编码: 100120

电 话: (010) 82282302 (主编室)

(010) 82282300 (编辑室)

82282301

82282329

(010) 82282326 (市场部)

传 真: (010) 82282289

电子邮箱: cndj2009@gmail.com

cndj@newdrug.cn

网 址: http://www.newdrug.cn

印 刷: 北京军区空军司令部印刷厂

发 行: 国内: 北京报刊发行局

国外: 中国国际图书贸易总公司

邮发代号: 82-488

国外代号: M4240

订 阅: 全国各地邮局

广告经营许可证号: 京西工商广字第8038号

国内定价: 每期12.00元, 全年288.00元

刊 号: ISSN 1003-3734

CN 11-2850/R

刊 期: 2010年第19卷第24期

出版日期: 2010年12月30日

版 权: 2010年版权归《中国新药杂志》

有限公司所有

# 目 录

- 卷首语 ..... 李国庆 (2211)
- 世界新药之窗 ..... (2212)
- 特别关注  
创新药物研发心得及展望 ..... 陈伟 (2217)
- 新药述评  
慢性特发性血小板减少性紫癜治疗药物罗米司亭和艾曲波帕 ..... 姚远兵, 王玲, 夏悦等 (2221)
- 新药研发论坛  
我国医药研发投入存在的问题及对策 ..... 孙燕, 孙利华 (2226)  
中外创新药物研发能力比较分析——基于医药技术创新评价体系的实证研究 ..... 姚雪芳, 丁锦希, 邵蓉等 (2231)  
《专利法》与《专利法实施细则》修改分析及对医药企业的影响 ..... 张清奎 (2240)  
贝叶斯混合处理比较及WinBUGS实现 ..... 廖炜圻, 陈平雁 (2244)
- 新药申报与审评技术  
药品注册申报资料的现状与问题(一)——基本信息和管理证明性文件 ..... 冯毅, 刘璐, 萧惠来等 (2249)  
药品注册申报资料的现状与问题(二)——化学药品药学研究 ..... 刘璐, 程鲁榕, 萧惠来等 (2251)  
药品注册申报资料的现状与问题(三)——中药、天然药物药学研究资料 ..... 田恒康, 萧惠来, 程鲁榕等 (2254)  
药品注册申报资料的现状与问题(四)——药理毒理研究资料 ..... 程鲁榕, 萧惠来, 田恒康等 (2255)  
药品注册申报资料的现状与问题(五)——生物等效性试验 ..... 萧惠来, 程鲁榕, 田恒康等 (2258)  
创新性药物非临床安全性评价的基本要点 ..... 彭健 (2261)
- 重大新药创制专项巡礼  
中成药再评价方法与策略研究 ..... 杨明, 伍振峰, 王芳等 (2267)  
药物杂质的毒理学评价要求及进展 ..... 祝清芬, 李涛, 国明等 (2271)
- 综述  
抗肿瘤创新药物研究进展 ..... 张万年, 缪震元 (2277)  
小分子肿瘤血管破坏剂研究进展 ..... 冯腾, 耿美玉, 李静 (2285)  
国际抗高血压新药研发进展 ..... 杜海洲, 张建平, 吕婷等 (2290)  
药物毒理学研究进展 ..... 张晓芳, 袁伯俊, 陆国才等 (2298)
- 临床研究  
那屈肝素钙治疗糖尿病下肢动脉疾病 Fontaine II 期患者疗效 ..... 姜涛, 文祺, 宋秀霞等 (2303)  
曲马多复合托烷司琼对腰-硬联合麻醉并发寒战的疗效 ..... 孔雪, 陈晓光, 高云霞 (2308)  
糖肾康颗粒 I 期临床试验研究 ..... 马松涛, 刘冬志, 邓晶晶等 (2312)  
屈螺酮炔雌醇片在人工流产后应用的临床观察 ..... 吴丹梅, 金松 (2316)
- 实验研究  
洛伐他汀对胶原性关节炎大鼠血清细胞因子的影响 ..... 赵征, 王炎焱, 黄峰等 (2319)  
谷胱甘肽复方注射液治疗猪血清致大鼠肝纤维化的药效研究 ..... 梁跃东, 李伟, 曾经章等 (2323)  
抗疟活性化合物—3-[4-(7-氯喹啉-4-基)咪唑-1-基]丙酸的合成与结构鉴定 ..... 王涛, 吴爱芝, 陈传兵等 (2328)  
红海槐内生真菌 BGD22 抑菌活性成分的初步研究 ..... 张庆华, 田峰, 李谦等 (2331)
- 其他  
《中国新药杂志》2010年第19卷文题索引 ..... (2336)

[期刊基本参数]

CN11-2850/R\*1992\*sm\*A4\*134\*zh\*P\*Y 12.00\*\*26\*2010-24

责任编辑 王宇梅 英文审校 魏尔清 杜小莉



中国新药杂志  
CHINESE JOURNAL OF NEW DRUGS  
Semimonthly 1992年1月创刊  
Founded in January 1992

CONTENTS

Directed by

State Food and Drug Administration

Sponsored by

China Medico-Pharmaceutical Science  
and Technology Publishing House  
China National Pharmaceutical Group Corp.  
Chinese Pharmaceutical Association

Editor-in-Chief SANG Guo-wei

Board Chairman/General Manager SONG Rui-lin

Director SONG Rui-lin WU Shao-zhen  
LI Shao-li DENG Jin-dong  
ZHU Jing-jin

Deputy General Manager FENG Lan WANG Zhe

Editorial Department Director HAN Pei

Editor and Publisher

Chinese Journal of New Drugs Co., Ltd.

Address

Floor 8 Lanyang Building  
No. 6 Beisanhuanzhonglu Xicheng District  
Beijing 100120 China  
Tel: (010) 82282302, 82282300  
82282301, 82282329  
(010) 82282326  
Fax: (010) 82282289  
http://www.newdrug.cn  
E-mail: cndj2009@gmail.com  
cndj@newdrug.cn

Printer

Military Headquarter's Printery of Beijing

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

December 30, 2010

Copyright

2010 by Chinese Journal of New Drugs Co., Ltd.

Drug discovery: our understanding and perspectives

.....CHEN Wei (2217)

The drugs in therapy of chronic idiopathic thrombocytopenic purpura:

romiplostim and eltrombopag.....YAO Yuan-bing, WANG Ling, XIA Yuc, et al (2221)

Pharmaceutical research and development investment in China: problems and countermeasures.....SUN Yan, SUN Li-hua (2226)

A comparison of innovative drug research and development abilities between China and foreign countries based on an evaluation system of pharmaceutical technology innovation.....YAO Xue-fang, DING Jin-xi, SHAO Rong, et al (2231)

Analysis of the revision of Chinese Patent Law and its detailed regulation of implementation: main points and influences on pharmaceutical enterprises.....ZHANG Qing-kui (2240)

Bayesian mixed treatment comparisons and implementation using WinBUGS

.....LIAO Wei-qi, CHEN Ping-yan (2244)

Common problems and status on drug registration application dossier (1):

regulatory information.....FENG Yi, LIU Lu, XIAO Hui-lai, et al (2249)

Common problems and status on drug registration application dossier (2): pharmaceutical study of chemical drugs

.....LIU Lu, CHENG Lu-rong, XIAO Hui-lai, et al (2251)

Common problems and status on drug registration application dossier (3): pharmaceutical study of Traditional Chinese Medicines

.....TIAN Heng-kang, XIAO Hui-lai, CHENG Lu-rong, et al (2254)

Common problems and status on drug registration application dossier (4): pharmacological and toxicological studies

.....CHENG Lu-rong, XIAO Hui-lai, TIAN Heng-kang, et al (2255)

Common problems and status on drug registration application dossier (5): bioavailability study.....XIAO Hui-lai, CHENG Lu-rong, TIAN Heng-kang, et al (2258)

Basic principles for nonclinical safety evaluation of the novel drug

.....PENG Jian (2261)

Method and strategy research on reevaluation of traditional Chinese drug

.....YANG Ming, WU Zhen-feng, WANG Fang, et al (2267)

Guidelines and recent developments of toxicological assessment of impurities in pharmaceutical products.....ZHU Qing-fen, LI Tao, GUO Ming, et al (2271)

Development of novel anticancer drugs

.....ZHANG Wan-nian, MIAO Zhen-yuan (2277)

Research progress in small molecule vascular disrupting agents

.....FENG Teng, GENG Mei-yu, LI Jing (2285)

Progress in the international development of new anti-hypertensive medicines

.....DU Hai-zhou, ZHANG Jian-ping, LU Ting, et al (2290)

Advances in the research of drug toxicology

.....ZHANG Xiao-fang, YUAN Bo-jun, LU Guo-cai, et al (2298)

Efficacy of nadroparin calcium in diabetic patients with lower extremity atherosclerotic disease (Fontaine stage II)

.....JIANG-Tao, WEN-Zhen, SONG Xiu-xia, et al (2303)

Effects of tramadol and tropisetron on shiver in patients undergoing combined spinal-epidural anesthesia..KONG Xue, CHEN Xiao-guang, GAO Yun-xia (2308)

Phase I clinical trial of Tangjiang-shenkang granule

.....MA Song-tao, LIU Dong-lian, DENG Jing-jing, et al (2312)

Application of drospirenone-ethinylestradiol tablets after artificial abortion

.....WU Dan-mei, JIN Song (2316)

Effect of lovastatin on serum cytokines in rats with collagen-induced arthritis

.....ZHAO Zheng, WANG Yan-yan, HUANG Feng, et al (2319)

Therapeutic effect of compound glutathione inosine injection on immunologically induced liver fibrosis in rats

.....LIANG Yue-dong, LI Wei, ZENG Jing-zhang, et al (2323)

Synthesis and structure identification of the anti-malarial agent 3-[4-(7-choloquinolin-4-yl) piperazin-1-yl] propanoic acid

.....WANG Tao, WU Ai-zhi, CHEN Chuan-bing, et al (2328)

Antibacterial metabolites of the endophytic fungus strain BGD22 from the stem of *Rhizophora stylosa* Griff.....ZHANG Qing-hua, TIAN Feng, LI Qian, et al (2331)