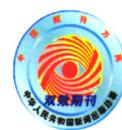


中国药学会系列期刊/《CAJ-CD》规范执行优秀期刊/美国《化学文摘》荷兰SCOPUS等国际著名检索系统收录
中国中文核心期刊 中国科技核心期刊 中国科学引文数据库来源期刊

CHINESE JOURNAL OF NEW DRUGS

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

中国新药杂志



7
2015
Vol.24 | No.7

- 探讨药物国际多中心临床试验设计的一种新方法SGDDP
我国化学仿制药生产企业申请达到WHO药品预认证标准的激励因素和技术差距研究
我国医药产业区域布局结构趋同性及影响因素研究
丹酚酸B的药动学及相关研究进展
甘草酸二铵对雷公藤甲素诱导肠通透增强及染色体损伤的保护作用

www.newdrug.cn

ISSN 1003-3734

9 771003 373156 07>

国家食品药品监督管理总局主管



•新药述评与论坛•

- 721 探讨药物国际多中心临床试验设计的一种新方法SGDDP..... 黄钦, 王骏, 曲荣华, 等
725 我国化学仿制药生产企业申请达到WHO药品预认证标准的激励因素和技术差距研究..... 黄宝斌, Christina Forge-Wimmer, 孙新生, 等
730 我国医药产业区域布局结构趋同性及影响因素研究..... 徐怀伏, 王欣
737 基于药品研发周期构建多向风险管理机制..... 李章明, 朱文良, 刘兰茹, 等
741 基于定价和补偿角度探讨罕用药价格规制体系..... 常峰, 商晓婷

•新药申报与审评技术•

- 745 试谈中药提取工艺中使用大孔吸附树脂纯化的研究要求与评价..... 宋丹, 张永文

•重大新药创制专项巡礼•

- 750 甘草酸二铵对雷公藤甲素诱导肠通透增强及染色体损伤的保护作用..... 淡墨, 文海若, 闻镍, 等
755 阿戈美拉汀微粒型口崩片的质量研究..... 周萧云, 张慧, 李志平, 等

•生物医药前沿•

- 760 离子交换层析法制备高纯度人凝血因子Ⅷ的研究..... 刘晓, 韩国德, 李青, 等

•综述•

- 765 新型化疗止吐药神经激肽-1受体拮抗剂的研究进展..... 孙秀波, 何祎晨, 刘蕾
771 PPAR γ激动剂的研究进展..... 张瑜, 邢志佳, 马宇衡, 等
778 微球在关节腔注射给药系统中的研究进展..... 王丽娟, 车柯科
782 含有缩酮(醛)的pH敏感聚合物作为药物载体的研究进展..... 王杨, 顾准, 王伟, 等
791 丹酚酸B的药动力学及相关研究进展..... 袁春平, 侯惠民, 区淑蕴
800 温度敏感型凝胶基质的研究进展..... 沈晶晶, 刘宏, 熊康萍

•临床研究•

- 804 盐酸戊乙奎醚片单次给药人体耐受性研究..... 雍小兰, 李楠, 杜晓琳, 等
808 他汀类药物治疗外周动脉粥样硬化的疗效比较..... 谢坚, 王玉凯, 邹燕, 等

•实验研究•

- 813 蝙蝠草中N⁶-(2-羟乙基)腺苷的提取分离及对小鼠睡眠的影响..... 陈玉皎, 孙嘉辰, 张晓倩, 等
818 聚缩酮PCADK的合成及胰岛素微球的制备与表征..... 张峰溥, 马鹏凯, 王正, 等
823 β-细辛醚对抑郁模型大鼠昼夜节律周期基因Per1表达的影响..... 董海影, 张春, 王俊苹, 等
827 盐酸可乐定缓释微丸制备工艺的探究..... 李见春, 张红敏, 孙宏张, 等
831 不同树脂对麻黄附子细辛汤中5种生物碱的洗脱性能比较..... 曹洪杰, 杨彬彬, 容蓉, 等
837 水杨酸甲酯立方液晶的研制..... 吴晓晴, 桂双英, 陈玉林, 等

CONTENTS

CHINESE JOURNAL OF NEW DRUGS

Founded in 1992, Semimonthly
Volume 24, Number 7
April 15, 2015

- 721 Statistical considerations on a new design method for multiregional clinical trial:
SGDDP HUANG Qin, WANG Jun, QU Rong-hua, et al
- 725 The incentives and technical gaps faced by Chinese manufacturers producing chemical generic medicines to achieve the standards of WHO Medicines Prequalification HUANG Bao-bin, Christina Forge-Wimmer, SUN Xin-sheng, et al
- 730 Structural convergence and influencing factors of Chinese pharmaceutical industry regional layout XU Huai-fu, WANG Xin
- 737 Constructing pharmaceutical R&D cycle-based multi-directional risk management mechanism LI Zhang-ming, ZHU Wen-liang, LIU Lan-ru, et al
- 741 Discussion about the orphan drug pricing regulation system from the perspective of pricing and reimbursement CHANG Feng, SHANG Xiao-ting
- 745 Requirement and evaluation of studies on using macroporous adsorption resin for further purification of extracts from Chinese herbal medicines SONG Dan, ZHANG Yong-wen
- 750 Protective effects of diammonium glycyrrhizinate on permeability increasing and chromosome breakage induced by *triptolide* DAN Mo, WEN Hai-ruo, WEN Nie, et al
- 755 Quality evaluation of agomelation orally disintegrating tablets with multi-particulate form ZHOU Xiao-yun, ZHANG Hui, LI Zhi-ping, et al
- 760 Preparation of high purity human coagulation factor VII using ion exchange chromatography LIU Xiao, HAN Guo-de, LI Qing, et al
- 765 Progress in research of neurokinin-1 receptor antagonists, new drugs for preventing and treating chemotherapy-induced nausea and vomiting SUN Xiu-bo, HE Yi-chen, LIU Lei
- 771 Research progress of PPAR γ agonists ZHANG Yu, XING Zhi-jia, MA Yu-heng, et al
- 778 Progress of microspheres as intra-articular injection drug delivery system WANG Li-juan, CHE Ke-ke
- 782 Progress in researches for pH-sensitive polymer with ketal (acetal) bonds used as drug carriers WANG Yang, GU Zhun, WANG Wei, et al
- 791 Progress in the pharmacokinetics and relative studies of salvianolic acid B YUAN Chun-ping, HOU Hui-min, OU Shu-yun
- 800 Progress in research of temperature-sensitive gel matrix SHEN Jing-jing, LIU Hong, XIONG Kang-ping
- 804 Study on safety and tolerability of single-dose of penehyclidine hydrochloride in healthy volunteers YONG Xiao-lan, LI Nan, DU Xiao-lin, et al
- 808 Comparison of efficacy of two statins for peripheral artery atherosclerosis XIE Jian, WANG Yu-kai, SHAO Yan, et al
- 813 Effects of N⁶-(2-hydroxyethyl)adenosine in *Cordyceps militaris* on the hypnotic of mice CHEN Yu-jiao, SUN Jia-chen, ZHANG Xiao-qian, et al
- 818 Synthesis of polyketal-PCADK and preparation and characterization of insulin microspheres ZHANG Feng-pu, MA Peng-kai, WANG Zheng, et al
- 823 Effect of β -asarone on expression of circadian genes *Per1* in rat model of depression DONG Hai-ying, ZHANG Chun, WANG Jun-ping, et al
- 827 Investigation of the preparation technique of clonidine hydrochloride sustained-release pellets LI Jian-chun, ZHANG Hong-min, SUN Hong-zhang, et al
- 831 Comparison of the elution properties of different resins for five alkaloids in Mahuang-fuzi-xixin decoction CAO Hong-jie, YANG Bin-bin, RONG Rong, et al
- 837 Preparation of cubic liquid crystal as a drug delivery system for methylsalicylate WU Xiao-qing, GUI Shuang-ying, CHEN Yu-lin, et al

Directed by: China 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-ji

Edited by: Editorial Board of Chinese Journal of New Drugs

Published by: Chinese Journal of New Drugs Co., Ltd.

Address: Room 1605, No.2 Ocean Cityscape, No.123 Zhongguancun Donglu,
Haidian District, Beijing 100086, China

Tel: (010)80442198 / 82282300 / 80442188 / 80442189 / 82282326

Fax: (010)82282289

Website: <http://www.newdrug.cn>

E-mail: bianjibu@newdrug.cn

Printer: Beijing Kexin 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: April 15, 2015

Copyright: 2015 by Chinese Journal of New Drugs Co.,Ltd.



泰勒宁®
氨酚羟考酮片

口服复方制剂

适用于各种中重度急慢性疼痛



- ② 双重机理，协同作用，中重度镇痛
- ② 复方制剂，口服给药
- ② 普通处方管理

【简要处方】

【成 份】本品为复方制剂。

其组分为：每片含盐酸羟考酮5mg，对乙酰氨基酚325mg。

【适 应】适用于各种中、重度急慢性疼痛。

【用法用量】成人常规剂量为每6小时服用1片，可根据疼痛程度和给药后反应来调整剂量。对于重度疼痛的患者或对阿片类镇痛药产生耐受性的患者，必要时可超过推荐剂量给药。

【不良反应】最常见的非严重的不良反应包括：头昏、眩晕、嗜睡、恶心、呕吐。运动时加重，休息时减轻。偶见精神亢奋、烦躁不安、便秘和皮肤瘙痒。

【批准文号】国药准字J20100119

【进口药品注册证号】H20100367

【进口生产企业】MALLINCKRODT INC. USA

【国内分包装企业】国药集团工业有限公司

请按医生处方购买和使用，详细处方资料请参阅产品说明书。

本广告仅供医学药学专业人士阅读。京药广审（文）第2014050375号



国药控股北京华鸿有限公司

地址：北京市东城区光明路11号天玉大厦508室

邮编：100061

电话：010-51902299

传真：010-51902111

国内定价：30.00元 国内统一刊号CN11-2850/R 邮发代号82-488 国外代号M4240