

NEW DRUGS

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

中国新药杂志  
二〇一九年  
第二十八卷  
第十九期  
第2305-2432页  
半月刊

CHINESE JOURNAL OF NEW DRUGS

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

# 中国新药杂志



19  
2019  
Vol.28 | No.19

- 德国临床效益评估对我国创新药医保准入临床价值评价的启示
- 2018年美国批准上市新药简析
- 新药研发中改盐案例分析
- 生理药动学模型结合体外相似性溶出实验预测国产口服苯唑西林钠溶出行为差异影响以及工艺合理性
- 头孢菌素杂质毒性的评价策略与方法

www.newdrug.cn

ISSN 1003-3734



国家药品监督管理局主管



万方数据

## •新药述评与论坛•

- 2305 抗CD47抗体、多肽类抗肿瘤药物专利发展状况分析.....代月函, 杨琳琳, 靳春鹏, 等  
2312 欧盟促进患者参与药物研发的实践及对我国的启示.....蒋玉霞, 茅宁莹  
2319 药物经济学评价在阈值缺失情况下缩小备选方案可选范围的方法研究.....高勇博, 肖瑶, 孙利华  
2323 德国临床效益评估对我国创新药医保准入临床价值评价的启示.....赵华婷, 颜建周, 邵蓉  
2327 2018年美国批准上市新药简析.....张华吉, 王磊, 朱凤昌, 等

## •新药注册与审评技术•

- 2332 新药研发中改盐案例分析.....叶旋, 张旻, 王庆利

## •重大新药创制专项巡礼•

- 2336 基于风险的C-QTc研究策略在药物心脏安全性评价中的应用.....汶柯, 王瑾, 柴栋, 等  
2341 基质辅助激光解吸电离质谱成像技术及其在新药研发中的应用.....林铭, 赵欣, 孙懿, 等  
2347 生理药动学模型结合体外相似性溶出实验预测国产口服苯唑西林钠溶出行为差异影响以及工艺合理性  
.....张斗胜, 王晨, 姚尚辰, 等  
2353 头孢菌素杂质毒性的评价策略与方法.....韩莹, 陈博, 刘颖, 等

## •综述•

- 2360 靶向NTRK, ROS1和ALK融合阳性实体瘤选择性激酶抑制剂entrectinib的研究.....王纪元, 李梁, 秦燕  
2367 新型降血脂药物的研究进展.....闵文剑, 齐炼文, 杨鹏

## •临床研究•

- 2375 LC-MS/MS法测定人血浆中沙芬酰胺浓度及其在中国健康人体内的药动学研究.....李蓉, 杨乐婷, 彭雅茹, 等  
2380 雌二醇通过PTEN/AKT信号通路促进自噬参与冠状动脉病变过程.....郭长磊, 陈恒文, 赵国安, 等

## •复方黄柏液涂剂研究及应用专栏•

- 2387 复方黄柏液涂剂湿敷对重症药疹皮损愈合的疗效观察.....冯西恩, 金外淑, 邵娟, 等  
2391 复方黄柏液涂剂湿敷治疗糖尿病足溃疡感染耐甲氧西林金黄色葡萄球菌的临床观察.....王宁, 高岩, 连晓彤, 等

## •实验研究•

- 2395 姜黄素水杨酰单酯增强肺癌A549细胞放射敏感性的研究.....张洁旻, 陈炳, 王飞羽, 等  
2400 注射用曲札芪昔对小鼠实验性脑水肿的影响.....杨旭娟, 施凯, 杨炳治, 等  
2405 去氢骆驼蓬碱衍生物DH-004不同途径给药的大鼠体内药动学研究.....高惠静, 巩月红, 卢帅, 等  
2411 采用Box-Behnken响应面法优化金鉴灵软膏的制备工艺及其初步药效研究.....张荣榕, 赵彧, 马翠霞, 等  
2420 安化黑茶预防性给药对APOE<sup>-/-</sup>小鼠动脉粥样硬化的影响.....张文将, 易健, 刘圆月, 等

## •药物安全与合理应用•

- 2428 基于决策树模型的口服铁补充剂治疗妊娠期缺铁性贫血的成本效果分析.....柴青青, 杜江洋, 张聪, 等

- 2305 Patent analysis on technology development of anti-CD47 antibody and peptide anti-tumor drugs  
DAI Yue-han, YANG Lin-lin, JIN Chun-peng, *et al*
- 2312 Promoting patient involvement in medicine R&D in European Union and its implications for China  
JIANG Yu-xia, MAO Ning-ying
- 2319 Narrowing optional intervention range by pharmacoeconomic evaluation without threshold  
GAO Yong-bo, XIAO Yao, SUN Li-hua
- 2323 The enlightenment of German clinical benefit evaluation on the clinical value evaluation of medical insurance access for innovative medicines in China  
ZHAO Hua-ting, YAN Jian-zhou, SHAO Rong
- 2327 Data analysis on new molecular entities approved by FDA in 2018  
ZHANG Hua-ji, WANG Lei, ZHU Feng-chang, *et al*
- 2332 Case studies of salt selection and optimization in drug development  
YE Xuan, ZHANG Min, WANG Qing-li
- 2336 Risk-based C-QTc research strategy in drug cardiac safety evaluation  
WEN Ke, WANG Jin, CHAI Dong, *et al*
- 2341 Matrix-assisted laser desorption ionization mass spectrometry imaging and its application in new drug research and development  
LIN Ming, ZHAO Xin, SUN Yi, *et al*
- 2347 Prediction of the difference in dissolution behavior of domestic oral oxacillin sodium and process rationality by physiological pharmacokinetic model combined with *in vitro* similarity dissolution test  
ZHANG Dou-sheng, WANG Chen, YAO Shang-chen, *et al*
- 2353 Prediction and evaluation of the toxicity of impurities in cephalosporins  
HAN Ying, CHEN Bo, LIU Ying, *et al*
- 2360 Study of a selective kinase inhibitor entrectinib targeting *NTRK*, *ROS1* and *ALK* fusion-positive solid tumors  
WANG Ji-yuan, LI Liang, QIN Yan
- 2367 Advances in studies on novel hypolipidemic drugs  
MIN Wen-jian, QI Lian-wen, YANG Peng
- 2375 Determination of safinamide in human plasma by LC-MS/MS and its pharmacokinetic study in Chinese healthy volunteers  
LI Rong, YANG Le-ting, PENG Ya-yu, *et al*
- 2380 Estradiol promotes autophagy through the PTEN/AKT signaling pathway to participate in coronary artery disease  
GUO Chang-lei, CHEN Heng-wen, ZHAO Guo-an, *et al*
- 2387 Observation on the therapeutic effect of moisten compression therapy of Compound Phellodendron Amurensis Liquid on healing of severe drug eruption  
FENG Xi-en, JIN Wai-shu, SHAO Juan, *et al*
- 2391 Clinical observation of smear method using Compound Cortex Phellodendri Liquid in the treatment of diabetic foot ulcer infection by MRSA  
WANG Ning, GAO Yan, LIAN Xiao-tong, *et al*
- 2395 Radiosensitizing effect of curcumin salicyloyl monoester on lung cancer cell line A549  
ZHANG Jie-min, CHEN Bing, WANG Fei-yu, *et al*
- 2400 The effect of 3, 5, 3', 4'-tetrahydroxystilbene-3'-O- $\beta$ -D-glucopyranoside injection on experimental cerebral edema in mice  
YANG Xu-juan, SHI Kai, YANG Bing-zhi, *et al*
- 2405 Pharmacokinetic study of harmine derivative DH-004 in rats by UPLC-MS/MS after different routes of administration  
GAO Hui-jing, GONG Yue-hong, LU Shuai, *et al*
- 2411 Optimization of preparation process of Jinjianling ointment by Box-Behnken response surface method and its preliminary  
ZHANG Rong-rong, ZHAO Yu, MA Cui-xia, *et al*
- 2420 Effect of prophylactic administration of Anhua dark tea on atherosclerosis in apolipoprotein E-knockout mice  
ZHANG Wen-jiang, YI Jian, LIU Yuan-yue, *et al*
- 2428 Cost-effectiveness analysis of oral iron supplements of iron-deficiency anemia in pregnancy based on decision tree  
CHAI Qing-qing, DU Jiang-yang, ZHANG Cong, *et al*

**Directed by:** National Medical Products 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  
**Edited by:** Editorial Board of Chinese Journal of New Drugs  
**Published by:** Chinese Journal of New Drugs Co., Ltd.  
**Address:** Room 317, No.3 Chengming Building, No.2 Xizhimen South Street, Xicheng District, Beijing 100035, China  
**Tel:** (010)52722697 / 52722651 / 52723707

**Website:** <http://www.newdrug.cn>  
**E-mail:** [bianjibu@newdrug.cn](mailto: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:** October 15, 2019  
**Copyright:** 2019 by Chinese Journal of New Drugs Co., Ltd.