

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:

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 QK1851860



CHINESE JOURNAL OF NEW DRUGS

# 中国新药杂志

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



19  
2018  
Vol.27 | No.19

FDA新药审评中补充资料的沟通交流机制研究及启示

HIV整合酶抑制剂药物及其专利研究

缩宫素注射液中三氯叔丁醇替代物的分子模拟

神经炎症对阿尔茨海默病中tau蛋白的影响

利用信息化技术实现临床试验用药品中心化管理质量与效率共赢

www.newdrug.cn

ISSN 1003-3734



9 771003 373187

19>

国家药品监督管理局主管



# 目 次

半月刊 1992年创刊

第27卷第19期 2018年10月15日出版

•新药述评与论坛•

- 2209 FDA新药审评中补充资料的沟通交流机制研究及启示..... 吕旭峰, 鞠梦琪, 袁利佳, 等

- 2214 HIV整合酶抑制剂药物及其专利研究..... 黄璐, 陆毅, 王卫彬, 等

- 2221 第5版和第6版《WHO儿童基本药物标准清单》及其与《国家基本药物目录》(2012年版)的对比分析及启示

..... 周瑞瑞, 谢晓慧, 陈哲, 等

- 2227 抗耐甲氧西林金黄色葡萄球菌的新型氟喹诺酮类药物德拉沙星..... 李双, 王琳, 杨君义, 等

•重大新药创制专项巡礼•

- 2232 全柱成像毛细管等电聚焦电泳法评价IL-15融和蛋白的电荷异质性..... 李响, 于雷, 郭莹, 等

- 2238 缩宫素注射液中三氯叔丁醇替代物的分子模拟..... 徐亦奇, 张媛, 孟凡翠, 等

•综述•

- 2245 神经炎症对阿尔茨海默病中tau蛋白的影响..... 张海波, 林爱花, 宫平, 等

- 2253 头孢洛扎/他唑巴坦与头孢他啶/阿维巴坦抗铜绿假单胞菌研究进展..... 高娅, 舒畅

- 2258 青蒿素类化合物对疟疾外其他疾病药效作用研究进展..... 王旭, 何林

- 2264 桑蚕资源在医药健康领域研究现状及应用前景分析..... 吕锐

- 2271 红芪多糖及其衍生物的化学结构与活性研究进展..... 强正泽, 王燕, 李硕, 等

•药物临床试验规范与进展专栏•

- 2281 利用信息化技术实现临床试验用药品中心化管理质量与效率共赢..... 牛晓也, 张晓婷, 高玉玲, 等

- 2286 基于风险的精细化控制静脉给药剂量的管理在零期临床试验中的应用..... 王泽娟, 刘晓娜, 刘晨, 等

•实验研究•

- 2291 柳氮磺胺吡啶在神经病理性疼痛大鼠中的镇痛作用..... 马龙飞, 陈国武, 陈明台, 等

- 2297 益母草碱溶液的降解动力学..... 周云珊, 尹丽娜, 张雅雯, 等

- 2302 硝苯地平包芯片的研制..... 商红玉, 任武贤

- 2308 积雪草酸衍生物的合成及其体外抗肿瘤活性研究..... 孟艳秋, 崔华博, 潘洪双, 等

- 2315 叶酸壳聚糖姜黄素pH敏感脂质体的制备及靶向性研究..... 刘小芳, 吴仪君, 石玮玮, 等

•药物安全与合理应用•

- 2322 注射用牛肺表面活性剂预防新生儿呼吸窘迫综合征的Meta分析..... 高晓燕, 高倩, 寇同欣, 等

- 2332 替加环素临床应用疗效及合理性评价..... 黄琪

[期刊基本参数] CN11-2850/R\*1992\*sm\*A4\*128\*zh\*P\* ¥ 30.00\*\*20\*2018-10

责任编辑 郑伟 英文审校 魏尔清 杜小莉 张鲸惊

万方数据

# CONTENTS

CHINESE JOURNAL OF NEW DRUGS

Founded in 1992, Semimonthly  
Volume 27, Number 19  
October 15, 2018

- 2209 FDA information request mechanism during new drug application review and some reference points for China LÜ Xu-feng, JU Meng-qi, YUAN Li-jia, et al
- 2214 HIV integrase inhibitor drugs and its patent research HUANG Lu, LU Yi, WANG Wei-bin, et al
- 2221 Comparative analysis of WHO Model List of Essential Medicines for Children (the 5th and 6th editions) and Chinese National Essential Medicine List (2012 edition) and its implication for China ZHOU Rui-rui, XIE Xiao-hui, CHEN Zhe, et al
- 2227 A novel fluoroquinolone antibiotic for methicillin-resistant staphylococcus aureus: delafloxacin LI Shuang, WANG Lin, YANG Jun-yi, et al
- 2232 Charge heterogeneity evaluation of IL-15 fusion protein by capillary isoelectric focusing-whole column imaging detection LI Xiang, YU Lei, GUO Ying, et al
- 2238 MD simulation of the substitutes of chlorobutanol in the oxytocin injection solution XU Yi-qi, ZHANG Yuan, MENG Fan-cui, et al
- 2245 The effect of neuroinflammation on tau pathology in Alzheimer's disease ZHANG Hai-bo, LIN Ai-hua, GONG Ping, et al
- 2253 Progress in researches for ceftolozane/tazobactam and ceftazidime/avibactam against *Pseudomonas aeruginosa* GAO Ya, SHU Chang
- 2258 Research progress on the pharmacological action of artemisinin beyond antimalarial WANG Xu, HE Lin
- 2264 Analysis on current research and application prospect of *Antheraea pernyi* in medical in health fields LÜ Rui
- 2271 Structure and activity of Hedysari Radix polysaccharides and its derivatives QIANG Zheng-ze, WANG Yan, LI Shuo, et al
- 2281 Realizing central investigational products management of high quality and high efficiency using information system NIU Xiao-ye, ZHANG Xiao-ting, GAO Yu-ling, et al
- 2286 Risk-based control for precise dosage in intravenous administration of anti-tumor drug phase 0 clinical trials WANG Ze-juan, LIU Xiao-na, LIU Chen, et al
- 2291 Analgesic effect of sulfasalazine on neuropathic pain in rats MA Long-fei, CHEN Guo-wu, CHEN Ming-tai, et al
- 2297 Degradation kinetics of leonurine solution ZHOU Yun-li, YIN Li-na, ZHANG Ya-wen, et al
- 2302 Study on the preparation of nifedipine package tablet SHANG Hong-yu, REN Wu-xian
- 2308 Synthesis and anti-tumor activity of novel asiatic acid derivatives *in vitro* MENG Yan-qi, CUI Hua-bo, PAN Hong-shuang, et al
- 2315 Preparation of folic acid chitosan curcumin pH sensitive liposomes and investigation of their targeting effect LIU Xiao-fang, WU Yi-jun, SHI Wei-wei, et al
- 2322 A Meta-analysis of prophylactic treatment with calf pulmonary surfactant for injection for neonatal respiratory distress syndrome GAO Xiao-yan, GAO Qian, KOU Tong-xin, et al
- 2332 Clinical application efficacy of tigecycline and rationality evaluation HUANG Qi

Directed by: State 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

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

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, 2018

Copyright: 2018 by Chinese Journal of New Drugs Co.,Ltd.



中国化学制药行业  
优秀产品品牌



## 作用位点明确有效 的胶质瘤治疗药

蒂清

**替莫唑胺胶囊**  
TEMOZOLOMIDE CAPSULES



• 针对脑肿瘤细胞DNA起效 • 骨髓抑制轻微且可逆 • 口服方便，吸收迅速

天士力健康热线 800-818-9818 400-618-9818 欢迎登陆大健康网 [www.dajiankang.com](http://www.dajiankang.com)

国药准字 H20040637 苏药广审(文)2017120659号 本广告仅供医学药学专业人士阅读 禁忌：1. 对替莫唑胺胶囊或达卡巴嗪(DTIC)过敏者禁用。2. 妊娠期禁用。3. 严重骨髓抑制的患者禁用。不良反应：轻微恶心、呕吐、便秘等。其它详见说明书。



万方数据

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