

半月刊  
1992年1月创刊  
2024年9月 第33卷 第17期  
(总第612期)  
2024年9月5日出版

中国药业  
ZHONGGUO YAOYE

CHINA PHARMACEUTICALS

## 目次

### 特别策划

·国家药监局重点实验室·麻精药品质量研究专题·

咪达唑仑原料药及其注射液中醛基类基因毒性杂质测定与含量比较

..... 匡鑫玉,程义,沈丹丹,徐琛,张伟(1)

PLGA-Tf纳米递药系统合成及防滥用性能评价..... 田金明,谢莉,唐华,彭金林,朱小康,陈竹(6)

枸橼酸舒芬太尼绿色合成工艺优化..... 王辉,曾令高,赵俊豪,谷桐薇,高梓真,杨相平(11)

致孔剂及其用量对盐酸吗啡渗透泵片体外释放度的影响

..... 张玲玲,阙晓,蒲婷,杨宇林,王书兰,罗立骏,侯立新(16)

电感耦合等离子体发射光谱法测定富马酸奥赛利定注射液中24种元素含量及其胶塞迁移量

..... 陈菲,任学毅,胡幸,陈竹,詹宇杰,王琳,武静文(20)

### 药事管理

基于HACCP管理法的多院区药学人员培养质量控制体系探索

..... 沈超,刘可欣,秦薇,陈铭鑫,杨嘉雯,王雪彦(25)

家用制氧机适用GB 9706.1—2020及其系列标准的设计变更探讨

..... 周美玲,江潇,官辉,兰婉玲,侯丽华,刘洋(29)

粤港澳大湾区药品监管规则分析..... 李立婕,张屿峰,何燕(32)

疫苗生产企业管理评审优化策略研究..... 王晔,罗静,钱正旭(36)

皮肤外用半固体制剂生物等效性试验的常见问题与关注点..... 成玘,叶丽卡,段炼,谢志红(39)

多学科协作品管圈提升静脉用药调配中心处方前置审核质量实践与效果..... 李杰,曹景超(42)

PDCA循环法改善住院患者静脉输液合理用药效果评价..... 严大鹏,陈继滨,彭昱,曹畅,叶岩荣,沈贇(46)

### 药学论著

高分辨液质联用技术评价半夏及其炮制品硫熏前后的品质..... 徐丹洋,张金星,张志同,王舒,朱琳(50)

差异表达微小核糖核酸在子宫内膜异位症中的诊断价值及调控机制

..... 李甘,徐颖,王峰,陆晓凡,杨渊(56)

壁虎多肽混合物对人非小细胞肺癌H1299细胞增殖和凋亡的影响..... 姚志新,刘嘉欣,朱桂芬,黄慧贤,陈少娜(61)

心脉舒一号口服液治疗心脏病分子机制网络药理学研究..... 唐勇琛,张洪平,樊玲凤,杨玉竹,张亚洲(66)

生产工艺对注射用奥扎格雷钠澄清度的影响研究..... 胡雯,何人可,陈永盛,勾磊,周爱玲,胡赛赛(73)

超高效液相色谱串联质谱法考察大鼠体内索凡替尼药代动力学..... 董清科,李刚,梁秀芳,秦永平(76)

### 检验检测

温胆汤颗粒剂质量评价方法的建立..... 许淑美,王婉怡,李航飞,郭国富,朱志军(81)

补肺防感合剂质量标准提升研究..... 徐江,姚晓,李均艳,刘辉,徐方铭,何一琴(87)

高压放电法检测玻璃安瓿密封性及其影响因素分析..... 李小伟,雷秀丽,胡佳音,李辉(91)

康寿丸质量标准提升研究..... 程宏辉,江涛,曾晨,苏锐辉,栗建明,顾利红,汤迎湛,陈丽斯(96)

罗红霉素胶囊微生物限度检查方法适用性研究..... 马鹏飞,贾萌,闵红,李翠,杨晓莉,由亚宁(100)

电位滴定法测定能力验证样品含量的不确定度评定..... 杨梅,伍良涌,李玮玲,邱娟(104)

## 临床研究

头孢他啶阿维巴坦与多黏菌素 B 治疗耐碳青霉烯类铜绿假单胞菌感染疗效比较

..... 刘昌伟,王小华,方玲,陈强,胡立芬(108)

微创注入肺表面活性物质技术联合咖啡因治疗新生儿呼吸窘迫综合征临床观察

..... 孙翠翠,刘金凤,吴爱华,刘玉晔,刘芳(111)

布托啡诺注射液对小儿扁桃体切除术后应激反应、苏醒期躁动及血清相关因子水平的影响

..... 冯彦红,孙利红,付利英,张晓楠,成林树(114)

含贝达喹啉不同治疗方案对耐多药肺结核患者 QT 间期延长的影响因素分析

..... 周亮,邱颖峰,栗茜,彭舟(118)

## 药品评价

艾多沙班治疗癌症相关静脉血栓栓塞症的快速卫生技术评估 ..... 孟佳佳,王陈萍,王丹丹,陈敏,窦志华(122)

沙库巴曲缬沙坦治疗慢性心力衰竭合并 2 型糖尿病有效性及安全性 Meta 分析

..... 陈春燕,陈金凤,付海坤,杨东亮,赵海霞,朱青梅(127)

基于 FAERS 的恩曲替尼药品不良事件信号挖掘 ..... 胡晔,黄磊,张琳琳,吴慧,缪阳,尹存林(134)

## 药学监护

1 例苯磺顺阿曲库铵致过敏性休克病例报道与分析 ..... 于竹君,李丹丹,钟思雨,王建莉(138)

1 例复方聚乙二醇电解质散( I )致心律失常病例分析 ..... 奚军伟,孙辉,戴洁,侯少平,王维(141)

## 综述

瑞香狼毒的化学成分及药理学和毒性作用研究进展 ..... 梁建娣,宋三孔(143)

药用复合膜安全性影响因素分析 ..... 王子梦,马宁,王春霞,冯毅,耿燕(147)

儿童非伤寒沙门菌胃肠炎抗感染治疗研究进展 ..... 李高芬,李俊,邱秀燕,杨雅(152)

# 中国药业

ZHONGGUO YAOYE

中国标准连续出版物号 ISSN 1006-4931  
CN 50-1054/R

主管单位 国家药品监督管理局

北京市西城区展览路北露园 1 号,100037

主办单位 重庆市药品监督管理局

重庆市渝北区食品城大道 27 号,401120

出版单位 中国药业杂志社

重庆市渝中区长江一路 61 号地产大厦  
1 号楼 19 层,400014

印刷单位 重庆市国丰印务有限责任公司

重庆市巴南区金竹工业园区金竹街 36 号,401320

国内发行 中国邮政集团公司重庆市分公司

重庆市渝中区嘉陵桥西村 83 号,400015

国外发行 中国国际图书贸易集团有限公司

北京市海淀区车公庄西路 35 号,100048

邮发代号 国内 78-130 国外 SM 5135

全国各地邮局(所)均可订阅

定 价 每册 10.00 元,全年 240 元

广告经营许可证号 (渝中市监)广登字(2020)第 002 号

开户银行 交通银行重庆渝中支行

账 号 500102120010149000795

顾问  
主任委员  
副主任委员

齐谋甲 樊代明 刘昌孝

陈地龙

黄世斌

高中

林能明

绳金房

徐维平

胡欣

蒋学华

苏乐群

封卫毅

汤华

王晓波

邵蓉

陈勇川

吴建龙

赵春景

史录文

廖丽燕

张蓉

赵春景

吕迁洲

张伶俐

李健

黄富宏

总编辑  
荣誉主编  
主 编  
执行主编  
副 主 编

马劲

张鹤镛

刘斌

郭澄

赵志刚

沈爱宗

刘松青

枉前

夏培元

葛卫红

王婧雯

叶云

王永庆

文爱东

邱峰

赖伟华

陈剑鸿

徐珽

赵荣生

周本杰

蓝柯

张健

卞晓岚

王凌

电 话 023-86592565

在线投稿 <http://www.zhongguoyaoye023.com>

## 声 明

1. 本刊刊发文章不代表本刊观点,版权归中国药业杂志社所有。未经授权,其他任何机构、个人不得转载、摘编。

2. 本刊被中国知网、万方数据、维普资讯等数据库和本刊网站全文收录,作者稿酬包括上述数据库和网站的使用报酬。若作者不同意收录,请在来稿时声明,以便妥善处理。

3. 本刊稿酬有现金和转赠《中国药业》两种支付方式,投稿本刊即视为同意本刊稿酬支付标准和支付方式。需现金支付稿酬的作者,请务必在投稿时声明或在论文刊发前来电来函告知。若无特殊声明,论文发表 3 月内,本刊将根据其稿酬金额自动转赠《中国药业》杂志。

期刊基本参数: CN 50-1054/R \* 1992 \* s \* A4 \* 152 \* zh \* P \* ¥ 10.00 \* \* 36 \* 2024-17

本期责任编辑 王海英 张小林

责任校对 温欣

英文编辑 张小林

# China Pharmaceuticals

September 5, 2024 Volume 33 – Number 17

## Contents

### ◆ Special Report

- NMPA Key Laboratory · Quality Study of Narcotic Drugs and Psychotropic Substances ·  
Determination and Comparative Analysis of Aldehyde Genotoxic Impurity in Midazolam Active  
Pharmaceutical Ingredients and Midazolam Injections  
..... KUANG Xinyu, CHENG Yi, SHEN Dandan, XU Chen, ZHANG Wei(1)  
Synthesis and Anti – Abuse Performance Evaluation of PLGA – Tf Nano Drug Delivery System  
..... TIAN Jinming, XIE Li, TANG Hua, PENG Jinlin, ZHU Xiaokang, CHEN Zhu(6)  
Optimization of the Green Synthesis Process of Sufentanil Citrate  
..... WANG Hui, ZENG Linggao, ZHAO Junhao, GU Xuwei, GAO Zizhen, YANG Xiangping(11)  
Effects of Pore – Forming Agents and Their Dosage on the *in Vitro* Release of Morphine Hydrochloride  
Osmotic Pump Tablets  
..... ZHANG Lingling, QUE Xiao, PU Ting, YANG Yulin, WANG Shulan, LUO Lijun, HOU Lixin(16)  
Content Determination of 24 Elements in Oliceridine Fumarate Injection and Rubber Stopper Migration  
by ICP – OES ..... CHEN Fei, REN Xueyi, HU Xing, CHEN Zhu, ZHAN Yujie, WANG Lin, WU Jingwen(20)

### ◆ Pharmaceutical Administration

- Establishment of Quality Control System for Multi – Hospital Pharmaceutical Personnel Training Based  
on HACCP Management Method  
..... SHEN Chao, LIU Kexin, QIN Wei, CHEN Mingxin, YANG Jiawen, WANG Xueyan(25)  
Design Changes for Household Oxygenator Applicable to GB 9706.1 — 2020 and Its Series of  
Standards ..... ZHOU Meiling, JIANG Xiao, GUAN Hui, LAN Wanling, HOU Lihua, LIU Yang(29)  
Drug Regulatory Rules in the Guangdong – Hong Kong – Macao Greater Bay Area  
..... LI Lijie, ZHANG Yufeng, HE Yan(32)  
Optimization Strategy of Management Review for Vaccine Manufacturers  
..... WANG Ye, LUO Jing, QIAN Zhengxu(36)  
Common Problems and Concerns in the Bioequivalence Trial of Semi – Solid Formulations for Topical  
Skin Application ..... CHENG Qi, YE Lika, DUAN Lian, XIE Zhihong(39)  
Practice and Effect of Multidisciplinary Collaborative Quality Control Circle in Improving the Quality of  
Pre – Prescription Review in PIVAS ..... LI Jie, CAO Jingchao(42)  
Evaluation of Effectiveness of PDCA Cycle Method in the Improvement of the Rational Use of  
Intravenous Infusion in Inpatients  
..... YAN Dapeng, CHEN Jiyun, PENG Gang, CAO Chang, YE Yanrong, SHEN Yun(46)

### ◆ Pharmacy Articles

- Quality Evaluation of Pinelliae Rhizoma and Its Processed Products Before and After Sulfur Fumigation  
Based on UPLC – Q – TOF – MS  
..... XU Danyang, ZHANG Jinxing, ZHANG Zhitong, WANG Shu, ZHU Lin(50)  
Diagnostic Value and Regulatory Mechanism of Differentially Expressed miR in Endometriosis  
..... LI Gan, XU Ying, WANG Feng, LU Xiaofan, YANG Yuan(56)  
Effect of Gecko Peptides Mixture on the Proliferation and Apoptosis of Human Non – Small Cell Lung  
Cancer H1299 Cells ..... YAO Zhixin, LIU Jiabin, ZHU Guifen, HUANG Huixian, CHEN Shaona(61)  
Molecular Mechanism of Xinmaishuyihao Oral Liquid in the Treatment of Heart Disease Based on  
Network Pharmacology ..... TANG Yongchen, ZHANG Hongping, FAN Lingfeng, YANG Yuzhu, ZHANG Yazhou(66)  
Effect of Production Process on the Clarity of Ozagrel Sodium for Injection  
..... HU Wen, HE Renke, CHEN Yongsheng, GOU Lei, ZHOU Ailing, HU Saisai(73)  
Investigation of Pharmacokinetics of Surufatinib in Rats by UPLC – MS / MS  
..... DONG Qingke, LI Gang, LIANG Xiufang, QIN Yongping(76)

### ◆ Inspection and Test

- Establishment of Quality Evaluation Method for Wendan Decoction Granules  
..... XU Shumei, WANG Wanyi, LI Hangfei, GUO Guofu, ZHU Zhijun(81)  
Improvement of Quality Standard of Bufeifanggan Mixture  
..... XU Jiang, YAO Xiao, LI Junyan, LIU Hui, XU Fangming, HE Yiqin(87)  
Package Integrity Test of Glass Ampoules and Its Influencing Factors by High – Voltage Leak  
Detection Method ..... LI Xiaowei, LEI Xiuli, HU Jiayin, LI Hui(91)  
Improvement of the Quality Standard of Kangshou Pills  
..... CHENG Honghui, JIANG Tao, ZENG Chen, SU Ruihui, LI Jianming, GU Lihong, TANG Yingzhan, CHEN Lisi(96)  
Suitability of the Microbial Limit Test Methods for Roxithromycin Capsules  
..... MA Pengfei, JIA Meng, MIN Hong, LI Cui, YANG Xiaoli, YOU Yaning(100)  
Evaluation of Uncertainty for the Determination of Proficiency Testing Samples by Potentiometric  
Titration ..... YANG Mei, WU Liangyong, LI Weiling, QIU Juan(104)

◆ **Clinical Research**

- Comparison of Efficacy of Ceftazidime / Averbactam and Polymyxin B in the Treatment of Carbapenem – Resistant *Pseudomonas Aeruginosa* Infection ..... LIU Changwei, WANG Xiaohua, FANG Ling, CHEN Qiang, HU Lifan(108)
- Clinical Observation of Less Invasive Surfactant Administration Technology Combined with Caffeine in the Treatment of Neonatal Respiratory Distress Syndrome ..... SUN Cuicui, LIU Jinfeng, WU Aihua, LIU Yuye, LIU Fang(111)
- Effect of Butorphanol Injection on Stress Response, Emergence Agitation, and Serum – Related Factor Levels in Children After Tonsillectomy ..... FENG Yanhong, SUN Lihong, FU Liying, ZHANG Xiaonan, CHENG Linshu(114)
- Influencing Factors of TQT Interval Prolongation in Patients with Multidrug – Resistant Pulmonary Tuberculosis Treated with Different Treatment Regimens Containing Bedaquiline ..... ZHOU Liang, QIU Yingfeng, SU Qian, PENG Zhou(118)

◆ **Drug Evaluation**

- Rapid Health Technology Assessment of Edoxaban in the Treatment of Cancer – Associated Venous Thromboembolism ..... MENG Jiajia, WANG Chenping, WANG Dandan, CHEN Min, DOU Zhihua(122)
- Efficacy and Safety of Sacubitril and Valsartan in the Treatment of Patients with Chronic Heart Failure and Type 2 Diabetes Mellitus: A Meta – Analysis ..... CHEN Chunyan, CHEN Jinfeng, FU Haikun, YANG Dongliang, ZHAO Haixia, ZHU Qingmei(127)
- Signal Mining of Entrectinib – Related Adverse Drug Events Based on FAERS Database ..... HU Ye, HUANG Lei, ZHANG Linlin, WU Hui, MIU Yang, YIN Cunlin(134)

◆ **Pharmaceutical Care**

- Anaphylactic Shock Induced by Muscle Relaxants: A Case Report and Analysis ..... YU Zhujun, LI Dandan, ZHONG Siyu, WANG Jianli(138)
- Arrhythmia Induced by Compound Polyethylene Glycol Electrolyte Powder( I ): A Case Analysis ..... XI Junwei, SUN Hui, DAI Jie, HOU Shaoping, WANG Wei(141)

◆ **Review**

- Research Progress on the Chemical Compositions, Pharmacological Effects, and Toxicity of *Stellera Chamaejasme* ..... LIANG Jiandi, SONG Sankong(143)
- Factors Affecting Safety of Medicinal Composite Films ..... WANG Zimeng, MA Ning, WANG Chunxia, FENG Yi, GENG Yan(147)
- Research Progress on Anti – Infective Treatment of Non – Typhoid *Salmonella* Gastroenteritis in Children ..... LI Gaofen, LI Jun, QIU Xiuyan, YANG Ya(152)



China Standard Serial Numbering ISSN 1006-4931  
CN 50-1054/R

Directed by National Medical Products Administration  
No.1, Beiluyuan, Zhanlan Road, Xicheng Dist., Beijing, China, 100053

Sponsored by Chongqing Municipal Drug Administration  
No.27, Food City Avenue, Yubei Dist., Chongqing, China, 401120

Edited & Published by China Pharmaceuticals Magazine Agency  
19th Floor, Building 1, Real Estate Mansion  
No.61, Changjiang No.1 St., Yuzhong Dist., Chongqing, China, 400014

Printed by Chongqing Guofeng Printing Co., Ltd.  
No.36, Jinzhu St., Jinzhu Industrial Park, Ba'nán Dist., Chongqing, China, 401320

Domestic Distributor  
Chongqing Branch of China Post Group  
No.83, West Village of Jialingqiao, Yuzhong Dist., Chongqing, China, 400015

Overseas Distributor  
China International Book Trading Corporation  
No.35, West Road of Chegongzhuang, Haidian Dist., Beijing, China, 100048

Domestic Code No. 78-130 Overseas Code No. SM 5135  
Price ¥ 10.00 for each book, ¥ 240 for whole year

Bank of Deposit  
Chongqing Yuzhong Subbranch of Bank of Communications  
Account Number 500102120010149000795

Consultants Qi Moujia Fan Daiming Liu Changxiao  
Director of the Editorial Board Chen Dilong  
Deputy Director of the Editorial Board  
Huang Shibin Hu Xin Wang Xiaobo  
Shi Luwen Lyu Qianzhou Gao Shen  
Jiang Xuehua Shao Rong Miao Liyan  
Zhang Lingli Lin Nengming Su Lequn  
Chen Yongchuan Zhang Rong Li Jian  
Sheng Jinfang Feng Weiyi Wu Jianlong  
Zhao Chunjing Huang Fuhong Xu Weiping  
Tang Hua

General Editor Ma Jin  
Honorary Editor – in – Chief Zhang Heyong  
Editor – in – Chief Liu Bin  
Executive Editors – in – Chief  
Guo Cheng Xia Peiyuan  
Wen Aidong Xu Ting  
Deputy Editors – in – Chief  
Zhao Zhigang Ge Weihong Qiu Feng  
Zhao Rongsheng Zhang Jian Shen Aizong  
Wang Jingwen Lai Weihua Zhou Benjie  
Bian Xiaolan Liu Songqing Ye Yun  
Chen Jianhong Lan Ke Wang Ling  
Wang Qian Wang Yongqing

Tel 023 – 86592565  
Web <http://www.zhongguoyaoye023.com>

Executive Editor Wang Haiying Zhang Xiaolin  
Executive Proofreader Wen Xin  
English Editor Zhang Xiaolin