

## 目 次

### 疫情防控专题

- 建立我国突发事件应急状态下的医疗产品紧急使用授权机制探讨 .....  
..... 王刚, 杨建红, 苏岭, 邵颖, 陈震, 高凯, 张彦彦, 陈江鹏, 张象麟 (254)  
献浆员中新型冠状病毒 SARS-CoV-2 中和抗体检测分析 .....  
..... 张黎, 聂建辉, 李倩倩, 吴佳静, 王威, 刘欢, 秦海洋, 王佑春, 黄维金, 侯继锋 (260)  
新发传染病相关的药品技术战略储备思考 .....  
..... 孙昱 (266)

### 监督管理

- 我国部分省市药品短缺现状研究及相关建议 .....  
..... 任亚男, 包晗, 王伟, 任磊, 王玉琨 (275)  
科学把握药典定位 创新品种遴选机制 .....  
..... 赵宇新, 麻广霖, 张栩峰, 张伟 (283)  
我国新药审评项目管理影响因素研究 .....  
..... 任爽, 董凌云, 张象麟 (288)  
关于药品抽检收样工作中常见问题探讨 .....  
..... 徐菲, 穆小洁, 宁烨, 吴良发 (298)

### 质量管理

- 药品批发企业质量管理体系运行中内审问题分析与对策研究 .....  
..... 刘华, 魏莉, 刘卫平, 陈佳, 刘颖, 郭盈彬, 翟晓艳 (302)  
新形势下提高基层药检机构质量管理工作水平的探讨 .....  
..... 陈娇, 郝翔 (306)  
关于综合性药品检验机构质量管理体系内部审核的探究 .....  
..... 于欣 (311)  
生物等效性试验健康受试者依从性风险管理研究 .....  
..... 王瑀琦, 张若明, 武志昂 (315)

质量评价

- 基于国家药品评价性抽验的鹅不食草质量问题分析 .....  
..... 刘杰, 过立农, 马双成, 郑健, 翁珂 (325)

药物研究

- 热分析技术研究物质纯度的探讨 .....  
..... 刘毅, 刘朝霞, 吴锐, 黄海伟, 严菁, 林兰 (330)  
加速溶剂萃取 - 高效液相色谱双波长法同时测定民族药广防风中 3 种成分的含量 .....  
..... 张荣林, 薛亚馨, 陆小康, 马双成, 翁珂, 林雀跃, 莫迎 (335)  
土庄绣线菊茶多酚抗氧化活性作用研究 .....  
..... 杨洋, 李珍, 杜之平, 丁华 (342)

研究进展

- 肝癌早期诊断标志物的研究进展 .....  
..... 王婷, 吴文晓, 马全涛, 耿兴超, 李波 (349)

不良反应

- 北京地区老年患者使用中药注射剂的不良反应分析 .....  
..... 陈浩, 冯雷, 赵业婷, 胡扬, 都丽萍 (357)  
84 例抗凝药物致不良反应的帕累托图分析 .....  
..... 马玉, 席宇飞, 康雷, 李琴, 范国荣, 熊学惠 (363)

医院药事

- 静脉药物配置中心优化工作流程效果的评价 .....  
..... 高湘曼, 朱凌云, 章云峰 (371)

## CONTENTS IN BRIEF

### Epidemic Prevention and Control

- On Establishing Emergency Use Authorization System of Medical Products under Emergency State in China**  
..... Wang Gang, Yang Jianhong, Su Ling, Shao Ying, Chen Zhen, Gao Kai, Zhang Yanyan, Chen Jiangpeng, Zhang Xianglin (254)
- Detection and Analysis of Novel Coronavirus SARS-CoV-2 Neutralizing Antibodies in Plasma Donors**  
.... Zhang Li, Nie Jianhui, Li Qianqian, Wu Jiajing, Wang Wei, Liu Huan, Qin Haiyang, Wang Youchun, Huang Weijin, Hou Jifeng (260)
- Considerations on Strategic Reserves of Pharmaceutical Technologies Related to Emerging Infectious Diseases**  
..... Sun Yu (266)

### Supervision & Administration

- On Current Situation of Drug Shortage in Several Provinces and Cities in China**  
..... Ren Ya'nan, Bao Han, Wang Wei, Ren Lei, Wang Yukun (275)
- Innovation of the Selection Procedure for the New Monograph of Chinese Pharmacopoeia Based on its Orientation**  
..... Zhao Yuxin, Ma Guanglin, Zhang Xufeng, Zhang Wei (283)
- On Influencing Factors of New Drug Evaluation Project Management in China**  
..... Ren Shuang, Dong Lingyun, Zhang Xianglin (288)
- On Common Problems in Drug Sampling and Sample Collection**  
..... Xu Fei, Mu Xiaojie, Ning Ye, Wu Liangfa (298)

### Quality Management

- Analysis and Countermeasures of Internal Audit Problems in the Operation of Quality Management System in Pharmaceutical Wholesale Enterprises**  
..... Liu Hua, Wei Li, Liu Weiping, Chen Jia, Liu Ying, Guo Yingshan, Zhai Xiaoyan (302)
- Reflections on Improving the Quality Management Level of Primary Drug Control Institutions under the New Situation**  
..... Chen Jiao, Hao Xiang (306)
- Exploration of the Internal Audit of Quality Management System in Comprehensive Drug Testing Institutes**  
..... Yu Xin (311)
- On Compliance Risk Management of Healthy Subjects in Bioequivalence Test**  
..... Wang Yuqi, Zhang Ruoming, Wu Zhiang (315)

## Quality Evaluation

### Analysis of Quality Problems of *Centipeda minima* Based on National Drug Evaluation Surveillance

..... Liu Jie, Guo Linong, Ma Shuangcheng, Zheng Jian, Zan Ke (325)

## Drug Research

### Purity Investigation by Thermal Analysis

..... Liu Yi, Liu Zhaoxia, Wu Rui, Huang Haiwei, Yan Jing, Lin Lan (330)

### Determination of Three Compounds in *Epimeredi indica* (L.) Rothm. by An HPLC Dual Wavelength Method Combined with Accelerated Solvent Extraction

..... Zhang Ronglin, Xue Yixin, Lu Xiaokang, Ma Shuangcheng, Zan Ke, Lin Queyue, Mo Ying (335)

### On Antioxidant Activity of Tea Polyphenols from *Spiraea pubescens* Turcz.

..... Yang Yang, Li Zhen, Du Zhiping, Ding Hua (342)

## Research Progress

### Progress in Biomarkers for Early Diagnosis of Hepatocellular Harcinoma

..... Wang Ting, Wu Wenxiao, Ma Quantao, Geng Xingchao, Li Bo (349)

## Adverse Reaction

### Analysis of Adverse Reactions to Traditional Chinese Medicine Injections Used by Elderly Patients in Beijing

..... Chen Hao, Feng Lei, Zhao Yeting, Hu Yang, Du Liping (357)

### Pareto Chart Analysis of 84 Cases of Adverse Reactions Caused by Anticoagulants

..... Ma Yu, Xi Yufei, Kang Lei, Li Qin, Fan Guorong, Xiong Xuehui (363)

## Hospital Pharmaceutical Affairs

### Evaluation of Effectiveness of the PIVAS Workflow Optimization

..... Gao Xiangmin, Zhu Lingyun, Zhang Yunfeng (371)