

## 目 次

### 监督管理

- PIC/S GMP 草药品生产附录与我国 GMP 中药饮片、中药制剂附录及相关法规的对比与思考 .....  
..... 吴晶, 王晗, 孙文, 李娜, 杨希凡, 王琳 (1345)
- 化学创新药不同注册申请阶段沟通交流中的药学问题一般性考虑 .....  
..... 任峰, 姜涛, 陈爱萍, 刘涓, 任连杰, 范乙 (1351)
- 药品进口备案现状与存在问题的分析 .....  
..... 李立婕, 陈继建, 高庆权, 漆亚乔 (1357)
- 从乙二醇、二甘醇污染事件探讨药用辅料质量管控重要性 .....  
..... 陆德, 许文艳, 裴宇盛, 肖妍 (1363)
- 基于应用数据分析的对照药材供应预警策略研究 .....  
..... 谢晶鑫, 程显隆, 乔婧, 魏锋, 赵宗阁, 孙会敏 (1371)
- 放射性药品检验实验室辐射安全管理探析 .....  
..... 裴云飞, 张文在, 王全柱, 张伟, 倪训松, 郭亚新 (1379)
- 以国际药品不良反应监测为引领的我国化妆品不良反应报告质量评估标准方法的研究与建立 .....  
..... 沈璐 (1387)

### 监管技术

- 药品监管中具引湿性化学对照品应用的建议 .....  
..... 刘毅, 吴静芳, 郭贤辉, 丁怡, 陈华, 宁霄, 曹进 (1399)
- 人凝血酶原复合物提取及其合并血浆制备血液制品的质量风险分析 .....  
..... 麻银林, 贺学锋, 勾洋梅, 孔丽亚, 山琳 (1404)
- 首批草酸艾司西酞普兰杂质 A 国家药品对照品的研制 .....  
..... 倪雪, 周晓力, 孙长迎, 许卉, 尹利辉 (1413)

- 氟伐他汀钠缓释片释放度测定的不确定度评定 .....  
..... 郭昭慧, 刘晶 (1421)
- 基于网络药理学探讨原花青素 A2 抗前列腺癌的作用机制 .....  
..... 常秀亭, 陈琳琳, 蔡家蕙, 寇力丹, 罗小菊, 王彬 (1429)

研究进展

- 民族药滇黄芩研究现状与思考 .....  
..... 宋伟, 严倩茹, 邬伟魁 (1438)
- 中药水蛭科属分类与物种名称的发展变化 .....  
..... 王文祎, 赵卫涛, 孙希, 杨金申, 杨瑶珺 (1447)

医院药事

- 医疗机构他汀类药品评价指标体系的构建 .....  
..... 庞静静, 钱雅婷, 袁冬冬, 刘伟 (1453)

## CONTENTS IN BRIEF

### Supervision & Administration

#### A Comparative Analysis and Reflection on the PIC/S GMP Annex for Herbal Medicinal Products Production with the Chinese GMP Appendices for Traditional Chinese Medicine Decoction Pieces and Preparations, and Related Regulations

..... Wu Jing, Wang Han, Sun Wen, Li Na, Yang Xifan, Wang Lin (1345)

#### General Considerations for Pharmaceutical Issues in the Communication of Innovative Chemical Drug at Different Application Stages for Registration

..... Ren Feng, Jiang Tao, Chen Aiping, Liu Juan, Ren Lianjie, Fan Yi (1351)

#### Analysis of the Current Situation and Existing Problems of Drug Import Filing

..... Li Lijie, Chen Jijian, Gao Qingquan, Qi Yaqiao (1357)

#### Exploring the Importance of Quality Control of Pharmaceutical Excipients from the Pollution Incident of Ethylene Glycol and Diethylene Glycol

..... Lu De, Xu Wenyuan, Pei Yusheng, Xiao Yan (1363)

#### Research on Optimizing Early-Warning Strategies for Supply of Reference Drug Based on Data Analysis

..... Xie Jingxin, Cheng Xianlong, Qiao Jing, Wei Feng, Zhao Zongge, Sun Huimin (1371)

#### Exploration of Radiation Safety Management in Radioactive Drug Testing Laboratories

..... Pei Yunfei, Zhang Wenzai, Wang Quanzhu, Zhang Wei, Ni Xunsong, Guo Yaxin (1379)

#### Research and Establishment of the Quality Assessment Standard Method of Cosmetic Adverse Reaction Reporting in China Based on the International ADR Monitoring

..... Shen Lu (1387)

### Regulatory Tehnology

#### Suggestions for the Hygroscopic Chemical Reference Substances in Drug Regulatory Application

..... Liu Yi, Wu Jingfang, Guo Xianhui, Ding Yi, Chen Hua, Ning Xiao, Cao Jin (1399)

#### Quality Risk Analysis of Human Prothrombin Complex Concentrate Extraction and Its Combination with Plasma for Blood Product Preparation

..... Ma Yinlin, He Xuefeng, Gou Yangmei, Kong Liya, Shan Lin (1404)

**Establishment of the First Batch of National Drug Reference Standard of Escitalopram Oxalate Impurity A**

..... Ni Xue, Zhou Xiaoli, Sun Changying, Xu Hui, Yin Lihui (1413)

**Evaluation of Uncertainty in the Releasing Rate Determination of Fluvastatin Sodium Sustained-release Tablets**

..... Gao Zhaohui, Liu Jing (1421)

**Exploring the Mechanism of Anti Prostate Cancer Effect of Proanthocyanidin A2 Based on Network Pharmacology**

..... Chang Xiuting, Chen Linlin, Cai Jiahui, Kou Lidan, Luo Xiaoju, Wang Bin (1429)

**Research Progress**

**Current Status and Insights of Ethnic Medicine *Scutellaria amoena* C. H. Wright**

..... Song Wei, Yan Qianru, Wu Weikui (1438)

**Research on Family and Genus Classification and Development of Species Names of Chinese Medicine Hirudo**

..... Wang Wenyi, Zhao Weitao, Sun Xi, Yang Jinshen, Yang Yaojun (1447)

**Hospital Pharmacy**

**Construction of Evaluation Index System of Statins in Medical Institutions**

..... Pang Jingjing, Qian Yating, Yuan Dongdong, Liu Wei (1453)