

药物评价研究

YAOWU PINGJIA YANJIU

第45卷 第8期 2022年8月

(月刊)

1978年创刊

主管

天津药物研究院(www.tjpr.com)

主办

天津药物研究院(www.tjpr.com)

中国药学会(www.cpa.org.cn)

编辑出版

《药物评价研究》杂志编辑部

地址:天津市滨海高新区惠仁道306号
(300462)

电话/传真:022-23006822

邮箱:der@tiprpress.com

网址:www.中草药杂志社.中国
www.tiprpress.com

印刷

天津市恒远印刷有限公司

国际标准连续出版物号

ISSN 1674-6376

国内统一连续出版物号

CN 12-1409/R

发行订阅

本刊编辑部

国内定价

每期 40.00 元

全年 480.00 元

出版日期

2022年8月8日

广告发布登记号

BH 2020-01

刊名题字

刘昌孝

本期责任编辑

李红珠

目 次

【药物非临床毒性病理学评价】

1461 致癌试验与人类风险评估无关的肿瘤概述

张亚群,葛建雅,闫振龙,钱 庄,李言川,胡文元,
钟小群,胡 静,陈晓俊,李一昊,彭瑞楠,王 娅,
李 慧,缪成贤,邵 薇,吕建军,李 华

1472 药物非临床安全性评价毒性病理学评价及病理学数据分析要点

陈晓俊,郑少秋,闫振龙,钱 庄,
胡文元,钟小群,胡 静,李一昊,彭瑞楠,王 娅,
李 慧,葛建雅,缪成贤,邵 薇,张亚群,吕建军

1480 毒性试验组织病理学结果有害作用判断概述

缪成贤,张亚群,闫振龙,钱 庄,胡文元,钟小群,
胡 静,陈晓俊,李一昊,彭瑞楠,王 娅,李 慧,
葛建雅,邵 薇,吕建军,李 华

1487 超微结构病理学在药物非临床安全性评价毒理学研究中的应用现状和关注点

王 娅,郑少秋,钱 庄,闫振龙,胡文元,钟小群,
胡 静,李一昊,陈晓俊,彭瑞楠,李 慧,葛建雅,
缪成贤,邵 薇,张亚群,吕建军

1493 非临床毒理学研究使用全切片图像进行组织病理学评价和同行评议的研究进展

葛建雅,李 慧,闫振龙,钱 庄,胡文元,钟小群,
胡 静,陈晓俊,李一昊,彭瑞楠,王 娅,缪成贤,
邵 薇,张亚群,吕建军

1500 药物非临床毒性试验周围神经系统组织病理学评估研究进展

李 慧,葛建雅,闫振龙,钱 庄,胡文元,钟小群,
胡 静,陈晓俊,李一昊,彭瑞楠,王 娅,缪成贤,
邵 薇,张亚群,吕建军

【审评规范】

1506 欧洲药品管理局(EMA)丹参根或根茎评估报告草案简介

萧惠来

1517 欧洲药物战略(2020)及其对中国医药领域的启示

宗 欣,赵雨虹,董江萍

【实验研究】

1522 基于网络药理学的不同方法炮制的何首乌肝毒性机制探讨及实验验证

高 峰,唐 瑜,张依娜,邹远荣,乔佳欣,卫培峰

1531 基于网络药理学的蒙药暖宫七味丸治疗原发性痛经作用机制及实验验证研究

张东旭,李 偲,
刘羽康,韩 峰,张爱杰,董世奇,樊慧蓉

1540 基于网络药理学与分子对接的温胆汤治疗冠心病合并抑郁作用机制探讨

祁 祥,卢健棋,温志浩,朱智德,王昱涵

1549 香附醇提物抗神经炎症活性及化学成分分析

张康丽,李凌宇,于 猛,张宏武,贾红梅,
邹忠梅

1558 携siRNA的丙交酯乙交酯共聚物-壳聚糖纳米载体的制备与表征

谭 涛,王梦洋,
陈承瑜,高 进,周毅生,曹 晖

1566 胆淤方对胆汁淤积小鼠胆汁酸代谢的影响

郝 娟,黄 恺,高国瑗,杨 涛,陶艳艳,
杨全军,吴 坚,刘成海

药物评价研究

YAOWU PINGJIA YANJIU
第45卷 第8期 2022年8月
(月刊)

1978年创刊

《药物评价研究》杂志第七届编辑委员会

名誉主编 桑国卫

主 编 王广基

副 主 编 (按拼音为序)

丁 健 李 波 刘 耀

黄璐琦 杨宝峰 周宏灏

甄永苏 王军志 汤立达

陈常青 司端运

委 员 (按姓氏拼音为序)

白 钢 曹 彩 岑小波 陈地龙

陈卫东 邸多隆 董江萍 杜晓曦

樊慧荣 范 益 高秀梅 郭 青

何光杰 何 新 何 毅 洪丽萍

侯文彬 胡 蓓 胡金芳 胡思源

黄 民 黄芝瑛 季宇彬 贾英杰

姜德建 江立新 蒋学华 李 川

李春如 李德坤 梁文波 廖明阳

刘岱琳 刘建忠 刘可春 刘克辛

刘晓东 姜建石 鲁 明 罗国安

罗晓健 吕 媛 马 璟 马双成

任晓文 沈竞康 沈晓红 沈志滨

施春阳 宋海峰 宋新波 唐 星

王春龙 王 捷 王 睿 王伟民

王玉芹 王 怡 王峥涛 吴春福

吴 迪 吴青业 徐为人 杨海淼

杨静玉 杨祥良 伊秀林 元唯安

张爱平 张兰珍 张 力 张秀娟

张艳军 张彦文 张 云 张振清

张志荣 张宗鹏 赵 玲 周 芳

周建平 朱五福

编辑部主任 刘东博

编辑部成员 兰新新 李红珠

1574 基于血浆代谢组学的新生化颗粒对急性血瘀大鼠作用机制研究

吕 玥, 孙纯勇, 李美琴, 印琴琴, 颜培正, 赵东升

1584 达肝素钠注射液质量评价

李 京, 龚益妮, 邓利娟, 张 佟, 范慧红

1592 不同干燥与提取方式处理的人源胎盘防治贫血活性差异研究

任季禹, 杨 凯, 靳 梦, 张姗姗, 于妙慧, 辛秀秀,

李晓彬, 刘可春, 张 云, 臧传宝, 盛文龙

1597 不同溶剂及提取方式对沉香精油成分的影响

戴伟杰, 李一峰, 陈志韶, 郑仲沐, 阚启鑫, 曹 庸

1608 HS-GC-MS/MS测定富马酸丙酚替诺福韦中微量的基因毒性杂质N-亚硝基二甲胺

孙 爽, 王 娜, 雷勇胜, 丁文字, 王志鹏,

张慕军, 潘 毅, 陈 蔚, 陈 华

1613 HPLC法测定盐酸乌拉地尔原料药中有关物质

王从娟, 陆赛花, 周自桂, 秦 勇

1622 复方丹参浸膏中低聚糖成分的分离与结构鉴定

张学敏, 王卫国, 牛 涛, 徐 波, 陈 红

【临床评价】

1627 阿加曲班联合阿替普酶治疗急性缺血性脑卒中的疗效及对患者抑郁相关指标的影响

吴力娟, 李 皓, 王京满, 李晓强, 魏玉清

1634 盐酸丙卡特罗口服或硫酸特布他林雾化联合布地奈德雾化治疗儿童咳嗽变异性哮喘的有效性及其经济性研究

陈秀峰, 王明晶, 肖 臻

1640 胰岛素强化治疗的2型糖尿病患者低血糖的危险因素分析及监控策略探讨

赖钦艺, 周洪仿, 周燕萍

1648 心通颗粒联合依洛尤单抗辅助治疗慢性心力衰竭合并高脂血症的疗效及对机体炎症介质的影响

何 蓉, 南昊宇, 李怀娜

1655 谷氨酰胺胶囊联合美沙拉秦肠溶片对溃疡性结肠炎患者疗效及对ESR、IGF-1水平的影响

刘小辉

【循证研究】

1660 免疫球蛋白辅助治疗扩张型心肌病疗效与安全性的Meta分析

刘璐瑶, 张 宁, 张艺凡, 焦雪妍, 兰真真,

郭 娇, 唐荣欣, 刘新灿

1671 胰岛素持续皮下输注与多次皮下注射对妊娠合并糖尿病患者影响的Meta分析

吴翠娟, 史晓霞, 李俊果, 杜会英, 朱晓明

【综述】

1679 间充质干细胞治疗特发性肺纤维化药理机制研究进展

高 雪, 慈小燕, 张英驰, 闫凤英

1684 药物安全性评价GLP规范与SOP的关系及完善质量体系初探

王 勇, 缪 峰, 吴 娴, 高嘉政, 杨昌雄,

王 丽, 张文婕, 徐书颖

1689 和厚朴酚的药动学研究进展

张明发, 沈雅琴

DRUG EVALUATION RESEARCH

Vol. 45 No. 8, August 2022

(Monthly)

Honorary Editor-in-Chief

SANG Guowei

Editor-in-chief

WANG Guangji

Associate Editors-in-chief

DING Jian LI Bo

LIU Yao HUANG Luqi

YANG Baofeng ZHOU Honghao

ZHEN Yongsu WANG Junzhi

TANG Lida CHEN Changqing

SI Duanyun

Directed by

Tianjin Institute of Pharmaceutical Research
(www.tjipr.com)

Sponsored by

Tianjin Institute of Pharmaceutical Research
(www.tjipr.com)
Chinese Pharmaceutical Association
(www.cpa.org.cn)

Edited and Published by

Editorial Office of Drug Evaluation Research
Address: 306# Huiren Road, Binhai District,
Tianjin 300462, China
Tel/ Fax: +86 22 2300 6822
URL: www.tiprpress.com
E-mail: der@tiprpress.com

Printed by

Tianjin Hengyuan Printing Co., Ltd.

Distribution

Self-Distribution

Standard Number

ISSN 1674-6376

CN 12-1409/R

Publication Date

August 8, 2022

Editor in Charge of This Issue

LI Hongzhu

Contents

- 1461** Overview of tumors of carcinogenicity studies irrelevant to risk assessment of humans ZHANG Yaqun, GE Jianya, YAN Zhenlong, QIAN Zhuang, LI Yanchuan, HU Wenyuan, ZHONG Xiaoqun, HU Jing, CHEN Xiaoqun, LI Yihao, PENG Ruinan, WANG Ya, LI Hui, MIAO Chengxian, SHAO Wei, LYU Jianjun, LI Hua
- 1472** Considerations of toxicologic pathology assessment and pathological data analysis during nonclinical safety evaluation of drugs CHEN Xiaoqun, ZHENG Shaoqiu, YAN Zhenlong, QIAN Zhuang, HU Wenyuan, ZHONG Xiaoqun, HU Jing, LI Yihao, PENG Ruinan, WANG Ya, LI Hui, GE Jianya, MIAO Chengxian, SHAO Wei, ZHANG Yaqun, LYU Jianjun
- 1480** Overview of determination of adverse effects of histopathological findings in toxicity studies MIAO Chengxian, ZHANG Yaqun, YAN Zhenlong, QIAN Zhuang, HU Wenyuan, ZHONG Xiaoqun, HU Jing, CHEN Xiaoqun, LI Yihao, PENG Ruinan, WANG Ya, LI Hui, GE Jianya, SHAO Wei, LYU Jianjun, LI Hua
- 1487** Current practices and points to consider for use of ultrastructural pathology in toxicology studies during nonclinical safety evaluation of drugs WANG Ya, ZHENG Shaoqiu, QIAN Zhuang, YAN Zhenlong, HU Wenyuan, ZHONG Xiaoqun, HU Jing, LI Yihao, CHEN Xiaoqun, PENG Ruinan, LI Hui, GE Jianya, MIAO Chengxian, SHAO Wei, ZHANG Yaqun, LYU Jianjun
- 1493** Research progress in utilizing whole slide images for histopathology assessment and peer review of nonclinical toxicology studies GE Jianya, LI Hui, YAN Zhenlong, QIAN Zhuang, HU Wenyuan, ZHONG Xiaoqun, HU Jing, CHEN Xiaoqun, LI Yihao, PENG Ruinan, WANG Ya, MIAO Chengxian, SHAO Wei, ZHANG Yaqun, LYU Jianjun
- 1500** Research progress in histopathology assessment of peripheral nervous system during nonclinical toxicity studies of drugs LI Hui, GE Jianya, YAN Zhenlong, QIAN Zhuang, HU Wenyuan, ZHONG Xiaoqun, HU Jing, CHEN Xiaoqun, LI Yihao, PENG Ruinan, WANG Ya, MIAO Chengxian, SHAO Wei, ZHANG Yaqun, LYU Jianjun
- 1506** Introduction to EMA's draft assessment report on *Salvia miltiorrhiza* radix et rhizoma XIAO Huilai
- 1517** Overview of Pharmaceutical Strategy for Europe (2020) and enlightenment to China's pharmaceutical field ZONG Xin, ZHAO Yuhong, DONG Jiangping
- 1522** Discussion and experimental verification of hepatotoxicity mechanism of *Polygonum multiflorum* processed by different methods based on network pharmacology GAO Feng, TANG Yu, ZHANG Yina, ZOU Yuanrong, QIAO Jiaxin, WEI Peifeng
- 1531** Mechanism of Nuangong Qiwei Pill for treatment of primary dysmenorrhea based on network pharmacology and experimental verification ZHANG Dongxu, LI Cai, LIU Yukang, HAN Feng, ZHANG Aijie, DONG Shiqi, FAN Huirong
- 1540** Mechanism exploring of Wendan Decoction in treatment of coronary heart disease combined with depression based on network pharmacology and molecular docking QI Xiang, LU Jianqi, WEN Zhihao, ZHU Zhide, WANG Yuhang
- 1549** Anti-neuroinflammatory activity and chemical constituents of ethanol extract from *Cyperus rhizome* ZHANG Kangli, LI Lingyu, YU Meng, ZHANG Hongwu, JIA Hongmei, ZOU Zhongmei
- 1558** Preparation and characterization of PLGA-chitosan nanoparticles carrying siRNA TAN Tao, WANG Mengyang, CHEN Chengyu, GAO Jin, ZHOU Yisheng, CAO Hui
- 1566** Effect of Danyu Recipe on bile acid metabolism in cholestasis mice HAO Juan, HUANG Kai, GAO Guoyuan, YANG Tao, TAO Yanyan, YANG Qianjun, WU Jian, LIU Chenghai

DRUG EVALUATION RESEARCH

Vol. 45 No. 8, August 2022
(Monthly)

Editorial Committee

of Drug Evaluation Research

Honorary Editor-in-Chief

SANG Guowei

Editor-in-chief

WANG Guangji

Associate Editors-in-chief

DING Jian LI Bo

LIU Yao HUANG Luqi

YANG Baofeng ZHOU Honghao

ZHEN Yongsu WANG Junzhi

TANG Lida CHEN Changqing

SI Duanyun

Members of Editorial Board

BAI Gang CAO Cai

CEN Xiaobo CHEN Dilong

CHEN Weidong DI Duolong

DONG Jiangping DU Xiaoxi

FAN Huirong FAN Yi

GAO Xiumei GUO Qing

HE Guangjie HE Xin

HE Yi HONG Liping

HOU Wenbin HU Bei

HU Jinfang HU Siyuan

HUANG Min HUANG Zhiying

JI Yubin JIA Yingjie

JIANG DeJian JIANG Lixin

JIANG Xuehua LI Chuan

LI Chunru LI Dekun

LIANG Wenbo LIAO Mingyang

LIU Dailin LIU Jianzhong

LIU Kechun LIU Kexin

LIU Xiaodong LOU Jianshi

LU Ming LUO Guoan

LUO Xiaojian LV Yuan

MA Jing MASHuangcheng

REN Xiaowen SHEN Jingkang

SHEN Xiaohong SHEN Zhibin

SHI Chunyang SONG Haifeng

SONG Xinbo TANG Xing

WANGChunlong WANG Jie

WANG Rui WANG Weimin

WANG Yuqin WANG Yi

WANG Zhengtao WU Chunfu

WU Di WU Qingye

XU Weiren YANG Haimiao

YANG Jingyu YANG Xiangliang

YI Xiulin YUAN Weian

ZHANG Aiping ZHANGLanzhen

ZHANG Li ZHANG Xiujuan

ZHANG Yanjun ZHANG Yanwen

ZHANG Yun ZHANG Zhenqing

ZHANG Zhirong ZHANG Zongpeng

ZHAO Ling ZHOU Fang

ZHOU Jianping ZHU Wufu

- 1574 Metabolomics analysis of Xinshenghua Granules for activating blood circulation on acute blood stasis rats
LÜ Yue, SUN Chunyong, LI Meiqin, YIN Qinqin, YAN Peizheng, ZHAO Dongsheng
- 1584 Quality evaluation of Dalteparin Injection
LI Jing, GONG Yini, DENG Lijuan, ZHANG Tong, FAN Huihong
- 1592 Anti-anemia activity of human placenta from different drying and extraction methods
REN Jiyu, YANG Kai, JIN Meng, ZHANG Shanshan, YU Miaohui, XIN Xiuxiu, LI Xiaobin, LIU Kechun, ZHANG Yun, ZANG Chuanbao, SHENG Wenlong
- 1597 Effects of different solvent and extraction methods on components of agarwood essential oil
DAI Weijie, LI Yifeng, CHEN Zhishao, ZHENG Zhongmu, KAN Qixin, CAO Yong
- 1608 Microdetermination of genotoxic impurity *N*-nitrosodimethylamine in tenofovir alafenamide fumarate by HS-GC-MS/MS
SUN Shuang, WANG Na, LEI Yongsheng, DING Wenyu, WANG Zhipeng, ZHANG Mujun, PAN Yi, CHEN Wei, CHEN Hua
- 1613 Determination of related substances in urapidil hydrochloride by HPLC
WANG Congjuan, LU Saihua, ZHOU Zigui, QIN Yong
- 1622 Isolation and structure identification of chemical constituents of oligosaccharide in compound Danshen extractum
ZHANG Xuemin, WANG Weiguo, NIU Tao, XU Bo, CHEN Hong
- 1627 Efficacy of agatrobaban combined with alteplase in treatment of acute ischemic stroke and its effect on depression-related indicators
WU Lijuan, LI Hao, WANG Jingman, LI Xiaoqiang, WEI Yuqing
- 1634 Efficacy and economy of oral procaterol hydrochloride or terbutaline sulfate nebulization combined with budesonide nebulization in treatment of cough variant asthma in children
CHEN Xiufeng, WANG Mingjing, XIAO Zhen
- 1640 Analysis of risk factors of hypoglycemia in patients with T2DM after intensive insulin therapy and discussion of monitoring strategies
LAI Qinyi, ZHOU Hongfang, ZHOU Yanping
- 1648 Efficacy of Xintong Granules combined with evolocumab in adjuvant treatment of chronic heart failure complicated with hyperlipidemia and its effect on inflammatory mediators
HE Rong, NAN Haoyu, LI Huaina
- 1655 Effect of Glutamine Capsule combined with Mesalazine Enteric Coated Tablets on patients with ulcerative colitis and effect on ESR and IGF-1
LIU Xiaohui
- 1660 Meta-analysis of efficacy and safety on immunoglobulin adjuvant therapy for dilated cardiomyopathy
LIU Luyao, ZHANG Ning, ZHANG Yifan, JIAO Xueyan, LAN Zhenzhen, GUO Jiao, TANG Rongxin, LIU Xincan
- 1671 Meta-analysis of continuous subcutaneous infusion and intermittent subcutaneous injection of insulin in treatment of patients with gestational diabetes mellitus
SHI Xiaoxia, WU Cuijuan, LI Junguo, DU Huiying, ZHU Xiaoming
- 1679 Research progress on pharmacological mechanism of mesenchymal stem cells in treatment of idiopathic pulmonary fibrosis
GAO Xue, CI Xiaoyan, ZHANG Yingchi, YAN Fengying
- 1684 Discussion on relationship between non-clinical safety evaluation GLP principles and SOP, and improvement of quality system
WANG Yong, MIAO Feng, WU Xian, GAO Jiazheng, YANG Changxiong, WANG Li, ZHANG Wenjie, XU Shuying
- 1689 Research progress on pharmacokinetics of honokiol
ZHANG Mingfa, SHEN Yaqin