



中文标题

检索

跨刊检索

近年我国中药新药注册申请不批准原因分析

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中文摘要:目的:分析近年来我国中药新药注册申请不批准的原因,探讨其中所反映的我国中药新药研发和注册管理方面可能存在的问题。方法:通过数据库检索2006—2008年国家食品药品监督管理局药品审评中心承办的中药新药注册申请中审评结论为“不批准”的全部品种,查询每个品种不批准的具体原因,并进行分类整理。统计涉及各类不批准原因的品种在全部不批准品种中所占的百分比,以进一步判读各类原因的主次关系。分析和探讨上述结果折射出的我国中药新药研发和注册管理方面可能存在的问题。结果:检索范围内审评结论为“不批准”的中药新药品种共247个。其中申请临床试验品种218个,不批准的原因共9大类,29种具体原因;申请上市品种29个,不批准的原因共5大类,9种具体原因。申请临床试验的中药新药品种不批准的主要原因包括研发立项问题、非临床有效性和非临床安全性问题。申请上市的品种不批准主要原因为临床有效性问题。结论:近年我国中药新药注册申请不批准涉及多方面的原因,其中主要原因包括有效性问题、安全性问题以及立项依据问题。这也一定程度上反映出当前我国中药新药研发和注册管理面临的问题。

中文关键词:新药 中药 注册

Analysis on reasons for disapproval of registration application of new traditional Chinese medicines in recent years

Abstract:Objective: To analyze reasons for disapproval of registration application of new traditional Chinese medicines in recent years and discuss potential problems occurring in R&D and registration administration of new traditional Chinese medicines in China. Method: All applications of new traditional Chinese medicines for registrations that had been disapproved by Center for Drug Evaluation of State Food Drug Administration from 2006 to 2008 were searched in data bank. Specific reasons for disapproval of each variety were inquired and sorted out. The statistics involved the proportion of each type (kind) disapproval reasons in all disapprovals in order to analyze which were the main reasons. The results were analyzed to find out potential problems occurring in R&D and registration administration of new traditional Chinese medicines in China. Result: There were totally 247 disapproved registration applications for new traditional Chinese medicines. Among them, there were 218 applications for clinical trials and 29 applications for launch in the market. There were 9 categories (29 types) of reasons for the applications for clinical trials applications, mainly including such problems as R&D proposal, non-clinical effectiveness and non-clinical safety, while there were 5 categories (9 types) of reasons for the applications for launch in the market, with clinical effectiveness as the main reason. Conclusion: There were many kinds of reasons for the disapproval registration applications of new traditional Chinese medicines in recent years in China, mainly including such problems as effectiveness, safety and proposal basis. This reflects problems occurring in R&D and registration administration of new traditional Chinese medicines in China to some extent.

keywords:new drug traditional Chinese medicine registration

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