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中药上市后临床再评价研究若干问题思考

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中文摘要:中药上市后再评价是一项复杂的、内容涵盖广泛的、实施难度大的研究工作,而我国上市后再评价起步较晚,从法规制度、技术规范等方面均有待完善。需要就中药上市后临床再评价过程中需注意若干问题,如再评价的法规要求、评价依据、评价对象选择等做初步探讨。

中文关键词:中药 上市后临床再评价

Thought on several problems of clinical reevaluation of post-marketing herb research

Abstract:The reevaluation of post-marketing herb is a complex research work, which concerns widely content and difficult to put it into practice. The starting of our country's reevaluation post-marketing herb was comparatively late. It should perfect it both in laws and regulations mechanism as well as technological specification. This article is try to focus on some attention problems in reevaluation of postmarketing herb process. Such as the laws and regulations demand, the basement and the subject of reevaluation of post-marketing herb.

keywords:traditional Chinese medicine re-evaluation of clinical postmarketing herbs

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