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维生素C注射液质量评价及现行标准分析

Quality Evaluation and Discussion on the Current Quality Standard of Vitamin C Injection

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中文摘要:

目的 评价国内维生素C注射液质量现状及存在的问题, 并根据探索性试验结果对现行质量标准提高提出一些建议。方法 在依据现行国家标准检验的基础上, 开展探索性研究, 对不同分析方法测得的结果进行分析。结果 按照现行标准检验309批样品, 合格率为100%。探索性研究显示, 采用HPLC测定有关物质, 68批样品中有6批杂质总量超过1.0%; 采用HPLC测定含量, 所检测的23批样品中有1批含量低于限度; 样品有关物质的含量、紫外吸收值、颜色呈正相关, 但没有线性关系, 样品溶液为黄色5号时杂质总量均超过1.0%; 产生颜色的物质之一可能由维生素C及降解产物缔合而成; 以硫代乙醇酸为抗氧化剂的样品的细胞毒性反应强于以盐酸半胱氨酸为抗氧化剂的样品的细胞毒性反应。结论 目前维生素C注射液的产品质量基本能符合现行标准要求, 现行标准基本可行, 但需进一步完善现行质量标准, 增加有关物质检查项, 提高控制颜色的吸光度限值, 建立专属性强的含量测定方法, 对毒性较大的辅料应慎用或限制加入量。

英文摘要:

OBJECTIVE To evaluate the quality of Vitamin C injection, and offer some suggestions on the current quality standards according to the exploratory results. METHODS On the basis of current quality standards, exploratory research methods were used to examine samples, analysis the results form the different methods. RESULTS The

309 batches of samples were tested under the current standard, with a pass rate of 100%. Exploratory research showed that 6 of 68 batches of samples' related substances were more than 1.0%, 1 of 23 batches of samples' content was below the limits determined by HPLC. The UV absorption and color of solution was positively correlated, but had no linear relationship. All of the tested samples' related substances were exceeded 1.0% when their colour were equal to NO.5 yellow standard colorimetric solution. One of the colored substances was probably associated by vitamin C and its degradation products. Samples with thioglycolic acid as antioxidant had stronger cytotoxicity than samples with hydrochloride cysteine as antioxidants. CONCLUSION The quality of Vitamin C injection can basically meet the current standards, but the current standards need to be further improved by adding check items of related substances, improving limits of absorption value for color check, establishing a highly specific method for the determination of content.

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