



中文标题

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量反应平行线法在溶栓胶囊蚓激酶效价测定方法学研究中的应用

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中文摘要: 目的: 建立蚓激酶的效价测定方法, 并引入生物检定统计法控制实验误差。方法: 用标准曲线法和生物检定的量反应平行线法统计计算效价, 从方法耐用性、专属性、线性范围、供试品处理方法、精密度、重复性、溶液稳定性、回收率、统计计算方法等方面对溶栓胶囊中蚓激酶效价测定的琼脂糖纤维蛋白平板法进行了方法学研究。结果: 不同应脂糖、不同纤维蛋白原对本法测定影响较小, 阴性对照无干扰; 本法线性范围为12.5~400 U, 精密度RSD 3.2%, 重复性RSD 8.3%, 回收率97.0%, RSD 16.6%; 供试品溶液在4℃下72 h内稳定; 用本法可以将测定误差由60%~70%降低到2%左右。结论: 琼脂糖纤维蛋白平板法可以快速、简便、准确地测定蚓激酶的活性, 用生物检定的量反应平行线法可以控制测定的误差。

中文关键词: 蚓激酶 效价 琼脂糖纤维蛋白平板法 生物检定 量反应平行线法

Using parallel line assay method based on quantitative responses in methodology evaluation for determining lumbrukinase potency in Rongshuan capsules

Abstract: Objective: To develop an assay methodology for determination of lumbrukinase potency in Rongshuan capsules. Method: The agarose-fibrin plate assay methodology for determination of Lumbrukinase potency in Rongshuan capsules was studied including durability, specificity, linearity range, product's handling method, accuracy, repetitiveness, solution stability, recovery and statistical method. The method of parallel line assay based on quantitative responses in statistical methods for biological assays was used in the statistics of potency assay. Result: The durability and specificity of assay accord with the requirement; The linearity range was 12.5~400 U, the RSD of accuracy tests was 3.2%, the RSD of repetitiveness tests was 8.3%, the solution is stable under 4℃ for 72 hours, the recovery rate was 97.0% and the RSD of recovery assays was 16.6%. Conclusion: The agar-fibrin plate assay is rapidly, feasible, simple, convenient and accurate way for determining the Lumbrukinase potency. The method of parallel line assay based on quantitative responses in statistical methods for biological assays can control the error of determination.

keywords: lumbrukinase potency agar-fibrin plate assay statistical methods for biological assays parallel line assay based on quantitative responses

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