

论文

重组人粒细胞巨噬细胞集落刺激因子的物质谱和毛细管电泳法

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摘要:

目的: 为准确分析重组人粒细胞巨噬细胞集落刺激因子(rHuGM-CSF)半成品及其制剂的纯度和表达的正确性。方法: 用毛细管区带电泳测定了2批rHuGM-CSF半成品和3批rHuGM-CSF注射液的纯度。用基质辅助激光解吸飞行时间质谱和电喷雾质谱测定了2批rHuGM-CSF半成品的分子量。用毛细管等电聚焦法测定了rHuGM-CSF半成品的等电点。结果: 2批半成品中1批含有少量二聚体, 且含有4个不同等电点的组分, 另1批表达不正确; 2批成品均存在大量杂质。结论: 发现有些rHuGM-CSF样品有生物学活性, 但表达不正确, 纯度也不高; 各分析方法是互补的, 不能相互替代。

关键词: 重组人粒细胞巨噬细胞集落刺激因子; 高效毛细管电泳; 基质辅助激光解吸飞行时间质谱; 电喷雾质谱; 毛细管等电聚焦

CHARACTERIZATION OF RECOMBINANT HUMAN GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTORS (rHuGM-CSF) BY BIOCHEMICAL MASS SPECTROMETRY AND CAPILLARY ELECTROPHORESIS

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Abstract:

AIM: To accurately determine the purity and correctness of expression for the bulk samples and preparations of rHuGM-CSF with biological activity. METHODS: The purities of two bulk samples and three preparations of rHuGM-CSF were determined by capillary zone electrophoresis (CZE), molecular weights of two rHuGM-CSF bulk samples by matrix assisted laser desorption ionization time of flight mass spectrometry (MALDI-TOF/MS) and electrospray ionization mass spectrometry (ESI/MS), and isoelectric points of rHuGM-CSF bulk sample by capillary isoelectric focusing (CIEF). RESULTS: One of the two bulk samples was expressed incorrectly, and the other contained a small amount of dimer, which composed of four components with different isoelectric points. There were large amounts of impurities in the two rHuGM-CSF preparations. CONCLUSION: The sample of rHuGM-CSF with biologic activity may be expressed incorrectly or contained impurities. The instrumental methods applied in this paper are complementary and we can not use one to replace the other.

Keywords: matrix assisted laser desorption ionization time of flight mass spectrometry electrospray ionization mass spectrometry recombinant human granulocyte-macrophage colony-stimulating factor capillary isoelectric focusing high performance capillary electrophoresis

收稿日期 1999-02-26 修回日期 网络版发布日期

DOI:

基金项目:

通讯作者: 罗国安

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