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#### 论文

重组人白细胞介素-11的胰蛋白酶切肽图分析

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摘要:

目的 建立标准肽图分析法,用于rhIL-11的质量控制。方法 应用Alliance HPLC系统及其温控自动进样器探索最 住胰蛋白酶切和色谱条件。结果 连续3批rhIL-11样品的RP-HPLC图谱完全一致,与rhIL-11对照品比较,有20个峰与对照品吻合,但第6峰的峰高和峰面积均明显较小,且在第9和第10峰之间多一个峰,说明rhIL-11样品蛋白质结构与对照品比较存在细小差别。这种差别经多肽片段分离和氨基酸序列测定证明是由于样品N端多2个氨基酸引起的。结论 本法精确度高、重复性好、自动化程度高,可用于rhIL-11的质量控制。

关键词: 重组人白细胞介素-11; 肽图; Alliance HPLC系统; 胰蛋白酶切

# PEPTI DE MAPPING ANALYSIS OF RECOMBINANT HUMAN INTERLEUKIN-11 BY TRYPTIC DIGESTION

RAO Chun-Ming; ZHANG Yi; HAN Chun-Mei; WANG Jun-Zhi

#### Abstract:

AIM To establish a standard method of peptide mapping analysis for quality control of rhIL-11. METHODS To find out the best tryptic digestion and chromatogram conditions by using Alliance HPLC system and automatic temperature-controlled injector. RESULTS Peptide mappings of three continuous batches of samples rhIL-11 are completely identical. Comparing with that of reference rhIL-11, 20 of the 21 peaks are all the same, but the area and height of the sixth peak are smaller than those of the reference product. Moreover, there is one extra peak between the ninth and tenth peak. It is stated that there are minor differences between the protein structure of the samples and that of the reference. The sixth and extra peaks of digested mixture of samples were separated and collected. Determination of amino acid sequence of two collected fragments indicates that there are two extra amino acids at the N-terminal of the sample, which leads to the detail differences. CONCLUSION The method has high degree of accuracy, automation and fine duplication, which can be applied for quality control of rhIL-11.

Keywords: peptide mapping alliance HPLC system tryptic digestion recombinant human Interleukin-

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重组人白细胞介素-11; 肽图;

▶ Alliance HPLC系统; 胰蛋白酶 切

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