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肿瘤治疗性多肽疫苗——重组人纽表位肽12质控方法的研究

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摘要:

目的建立重组人纽表位肽12质控方法和检定规程。方法采用FVB/N转neu基因小鼠,以ELISA法检测给药后小鼠的抗 ▶把本文推荐给朋友 体阳转百分率评价其生物学活性,用胃蛋白酶酶切分析肽图,用SEC-HPLC法测定抗原含量。结果与结论建立了重组 人纽表位肽12的生物学活性、肽图分析、抗原含量测定等质控方法及检定规程,并已用于重组人纽表位肽12产品的 检定。

关键词: 重组人纽表位肽12 质量控制和检定规程 生物学活性

Study on methods for quality control of recombinant human neu epitope peptide 12

JI Hong; WANG Jun-zhi; RAO Chun-ming; ZHANG Yi; WANG Min

Abstract:

AimTo establish methods and requirements for the quality control of recombinant human neu epitope peptide 12. MethodsBiological activity of recombinant human neu epitope peptide 12 was evaluated in FVB/N transgenic mice (TgN MMTVneu 202 Mul, Jackson Lab., USA) administered with samples. The percentage of antibody-positive mice detected by ELISA was used in the biological activity evaluation. The peptide map was performed by peptic digestion. The antigen content was determined by SEC-HPLC. Results and conclusionThe quality control methods, such as biological activity, peptide map, antigen content, and the requirements for the quality control of recombinant human neu epitope peptide 12 were established. The established methods and requirements were already used for the quality control of recombinant human *neu* epitope peptide 12 products.

Keywords: quality control and requirements biological activity recombinant human neu epitope peptide 12

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