

论文

重组人淋巴细胞功能相关抗原3-抗体融合蛋白质量控制方法与质量标准研究
重组人淋巴细胞功能相关抗原3-抗体融合蛋白质量控制方法与质量标准研究

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摘要:

研究建立重组人淋巴细胞功能相关抗原3-抗体融合蛋白(rhLFA3-IgG1)质量控制方法和质量标准。采用针对Jurkat细胞表面CD2分子的竞争结合试验测定融合蛋白的体外活性,以分子筛和离子交换色谱分别确定制品纯度,将制品还原、羧甲基化后再以胰蛋白酶裂解并经反相高效液相色谱进行肽图分析,采用ELISA法分别测定蛋白A与CHO宿主细胞蛋白残留量。建立了重组人淋巴细胞功能相关抗原3-抗体融合蛋白生物学活性、理化特性与残留杂质等质量控制方法和质量标准。所建立的质量控制方法和质量标准具有保证产品安全有效、质量可控的特点,可用于重组人淋巴细胞功能相关抗原3-抗体融合蛋白(rhLFA3-IgG1)的质量控制与产品检定。

关键词: 重组人淋巴细胞功能相关抗原3-抗体融合蛋白 质量控制 自身免疫疾病

Quality control methods and requirements for recombinant human lymphocyte function associated antigen 3 IgG1 fusion protein (rhLFA3-IgG1)

GAO Kai; HAN Chun-mei; DING You-xue; HOU Sheng; RAO Chun-ming; WANG Jun-zhi

Abstract:

To establish methods and requirements for quality control of rhLFA3-IgG1, biological potency of rhLFA3-IgG1 was determined by CD2 molecule competitive binding assay on Jurkat cell surface. Purity of rhLFA3-IgG1 was analyzed by SEC-HPLC and IEC-HPLC. Peptide mapping was performed by tryptic digestion and RP-HPLC after sample reduced and carboxymethylation by DTT and indoacetic acid, respectively. CHO host cell protein and Protein A residual were detected by ELISA separately. The quality control methods and requirements, such as biological potency, the physical-chemical characteristic of rhLFA3-IgG1 had been established. The methods and requirements for quality control of rhLFA3-IgG1 showed advantages of assuring the products safety and efficacy, which can be used for routine quality control of rhLFA3-IgG1.

Keywords: quality control autoimmune disease recombinant human lymphocyte function associated antigen 3 IgG1 fusion protein (rhLFA3-IgG1)

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