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注射用维生素B₆细菌内毒素检查法的研究

Bacteria Endotoxin Test of Vitamin B₆ for Injection

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英文关键词: [vitamin B₆ for injection](#) [bacterial endotoxin test](#) [interference test](#)

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中文摘要:

目的 建立注射用维生素B₆的细菌内毒素检查方法。方法 根据中国药典2010年版二部附录细菌内毒素检查法,采用2个不同厂家的鲎试剂对注射用维生素B₆进行研究。结果 注射用维生素B₆细菌内毒素检查限值为0.30 EU·mg⁻¹,其最大不干扰浓度为0.208 mg·mL⁻¹,用灵敏度为0.06 EU·mL⁻¹或更高灵敏度的鲎试剂可进行检验。结论 细菌内毒素检查法可用于注射用维生素B₆中内毒素的检查。

英文摘要:

OBJECTIVE To establish the bacterial endotoxin test of vitamin B₆ for injection. METHODS The experiment was carried out according to the appendix of ChP 2010 Vol II. tachypleus amabocyte lysate from two manufacturers were used to test the bacterial endotoxin. RESULTS The endotoxin limit of vitamin B₆ for injection was 0.30 EU·mg⁻¹. The reactions were not disturbed in 0.208 mg·mL⁻¹ for vitamin B₆, which was the maximum nondisturbing concentration. It was effective that endotoxin was tested by amebocyte lysate agent with the sensitivity of 0.06 EU·mL⁻¹ or much higher. CONCLUSION It is feasible to control quality of vitamin B₆ for injection by bacterial endotoxin test.

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