

论文

FTIR法用于药品检出菌与药品微生物检验洁净室环境菌的相关性考察

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摘要:

应用FTIR法对药品检出菌与微生物检验洁净室环境菌进行相关性考察, 通过临界匹配值法和聚类分析法比较药品检出菌与环境菌FTIR图谱的相似性; 构建了洁净室环境菌的FTIR光谱谱库, 确定了快速判断药品检出菌是否为环境菌污染的指标, 为药品无菌检查一次性报告的准确性提供了保证, 并可以实现对洁净室环境微生物的动态监控; 方法简便、准确、快捷, 易于在药品微生物控制中推广。

关键词: FTIR 药品无菌检查 微生物控制 洁净室 相关性

Correlation of bacteria in the contaminated drug and the environmental microbes in the clean room for pharmaceutical microbial test investigated by FTIR

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Abstract:

The FTIR method was used to investigate the correlation of bacteria in the contaminated drug and the environmental microbes in the clean room for pharmaceutical microbial test. The similarity of bacteria in the contaminated drug and environmental microbes was compared by critical hit value method and cluster analysis method. This constructed the FTIR spectra library of clean room environmental microbe, and determined the criterion to promptly judge if the bacteria isolated from pharmaceuticals were contaminated by environment or not, hence the exactness of "one-off report" of sterile test result can be guaranteed, and can be used for the dynamic monitoring of environmental bacteria of clean room. The method is proven to be simple, accurate and rapid, and can be easily spread to the pharmaceutical microbial control.

Keywords: pharmaceutical sterile test microbial control clean room correlation FTIR

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