

论文

多通道光纤化学传感器连续在位监测固体制剂的体外溶出度多通道光纤化学传感器连续在位监测固体制剂的体外溶出度

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摘要:

目的 为连续在位监测固体制剂的体外溶出度,自制多通道光纤化学传感溶出仪。方法 用自制光纤荧光溶出度监测仪与ZRS-4型智能溶出仪联用,连续在位监测氧氟沙星片、甲硝唑片、呋喃妥因肠溶片的体外溶出度,溶出曲线经微机从5种常用数学模型中根据相关系数R值,优选最佳模型进行拟合。结果 方法的回收率分别为97.4%~104.4%, 97.4%~103.8%, 96.6%~102.1%,日内、日间的RSD均小于5%。经与中国药典2000版方法及美国药典23版方法对照,各时间点药物累积溶出量和拟合后提取的参数均无显著性差异(P>0.05)。结论 本法简便、快速,结果准确、可靠,重现性好。

关键词: 光纤化学传感器 氧氟沙星 甲硝唑 呋喃妥因 溶出度 多通道光纤化学传感器溶出度监测仪

Continuous in situ monitoring of the dissolution rate of solid pharmaceutical preparations using a multiple channel fiber-optic chemical sensor

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Abstract:

Aim To study the dissolution rate of solid pharmaceutical preparation on-line, a multiple channel fiber-optic chemical sensor based on fluorescence multiple quenching (FOCSMQ) without filtering and sampling was made. Methods Using the multiple channel FOCSMQ linked with computer, the dissolution rates of ofloxacin tablets, metronidazole tablets and nitrofurantoin tablets were monitored continuously on-line. The instrument can give the sample data, display the real time curve and calculate the $T_{1/2}$ and T_d

automatically. A computer was used to select the best function from five common fitting models to fit the dissolution curve. Results The average recoveries of the FOCSMQ method were 97.4%-104.4%, 97.4%-103.8% and 96.6%-102.1%. The RSDs (N=6) of within-day and between-day were less than 5%. The parameters of the dissolution and all results of measurement using the instrument have no significant difference compared with the Chinese Pharmacopoeia (ChP) (2000) method and the United States Pharmacopoeia (USP) (23) method (P>0.05). It does not need sampling and dilution, and never contaminate sample. It can shorten time of the experiment. Conclusion The method is simple, rapid and reliable.

Keywords: ofloxacin metronidazole nitrofurantoin dissolution multiple channel fiber-optic chemical sensor dissolution monitor fiber optic chemical sensor

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