

不同厂家尼群地平片溶出度考察

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摘要

目的 考察不同厂家生产的尼群地平片的体外溶出度,为临床用药提供参考。方法 以0.1 mol·L⁻¹盐酸-乙醇溶液(体积比70:30)为溶出介质,采用紫外分光光度法测定溶出度;以质量分数为0.15%的吐温80水溶液为溶出介质,采用HPLC法测定溶出度;以不同质量分数的十二烷基硫酸钠水溶液、含质量分数为1.0%十二烷基硫酸钠的0.1 mol·L⁻¹盐酸溶液、pH 4.5醋酸钠缓冲液、pH 6.8磷酸盐缓冲液为溶出介质,采用紫外分光光度法测定溶出度;比较不同厂家尼群地平片的体外溶出度;用相似因子法评价尼群地平片在含质量分数为1.0% 十二烷基硫酸钠的0.1 mol·L⁻¹盐酸、pH 4.5醋酸钠缓冲液、pH 6.8磷酸盐缓冲液中的溶出行为。结果 溶出介质分别为0.1 mol·L⁻¹盐酸-乙醇溶液(体积比70:30)和质量分数为0.5%的十二烷基硫酸钠水溶液时,尼群地平片在60 min时的溶出度不小于60%。结论 pH值对尼群地平的溶出没有影响,不同厂家生产的尼群地平片的溶出度存在较大的差异。

关键词 [药剂学](#) [溶出度](#) [紫外分光光度法](#) [尼群地平](#)

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Dissolution study for nitrendipine tablets of different brands

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Abstract

Objective To study the dissolution behavior of nitrendipine tablets of five different factories. Methods 0.1 mol·L⁻¹ HCl-C₂H₅OH (V:V=70:30) was used as the dissolution media. The dissolution sample of nitrendipine tablets in vitro was determined by the UV spectrophotometric method. 0.15% Tween 80 was used as the dissolution media and the dissolution sample was determined by the high performance liquid chromatography method. The sodium dodecyl sulfate (SDS) solutions of different concentration, 0.1 mol·L⁻¹ HCl, pH 4.5 acetate buffer and pH 6.8 phosphate buffer with 1.0% SDS were used as dissolution media. The dissolution sample was determined by the UV spectrophotometric method. The data obtained was analyzed by the statistical method-similar factor method. Results The dissolution of nitrendipine tablets in 0.1 mol·L⁻¹ HCl-C₂H₅OH (V:V =70:30) and 0.5% SDS solution was both no less than 60% at 60 min. Conclusion pH has no influence on the dissolution of nitrendipine tablets. There is a great difference between the dissolution behavior of nitrendipine of different brands.

Key words [pharmaceutics](#) [dissolution](#) [UV](#) [nitrendipine](#)

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