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论文

地塞米松磷酸钠温度敏感原位凝胶的特性研究

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摘要：

本文以泊罗沙姆Pluronic F127为温度敏感原位凝胶材料，考察了Pluronic F127与Pluronic F68不同浓度处方对地塞米松磷酸钠温度敏感原位凝胶的胶凝温度、相转变温度、凝胶强度、稳态黏度、溶蚀和药物释放行为等特性的影响。采用试管倒转法测定胶凝温度；旋转流变仪测定相转变温度、弹性模量、稳态黏度等流变学参数；无膜溶出法测定凝胶的溶蚀行为；HPLC测定地塞米松磷酸钠的释放度。结果表明，随着处方中F127浓度的增高，凝胶的胶凝温度和相转变温度降低，黏度和弹性模量增加，溶蚀速率和药物释放速率减慢；而处方中F68对凝胶特性的影响与F127相反。温度敏感原位凝胶在低温时为牛顿流体，黏度很小；随着温度升高，黏度增大；当增至相转变温度附近，表现出典型的假塑性流体特征；药物释放速率受控于凝胶溶蚀速率，二者遵循零级动力学方程。处方中含F127 22.5% / F68 2.5%的地塞米松磷酸钠温度敏感原位凝胶的性质与临床治疗要求基本吻合，有望在临床中获得应用。

关键词： 温度敏感原位凝胶 泊罗沙姆 相转变温度 胶凝温度 稳态黏度 弹性模量

Characteristics of poloxamer thermosensitive *in situ* gel of dexamethasone sodium phosphate

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Abstract:

Thermosensitive *in situ* gel is a novel drug delivery system which can form gel *in situ* after injection of the polymer solution into the body and releases the drug in a controlled manner, thus provides a promising strategy for localized drug delivery. The aim of the present work is to investigate the characteristics including gelation temperature, sol-gel transition temperature (T_{s-g}), gel strength, stable viscosity, erosion and drug release behavior of the thermosensitive *in situ* gel which are composed of different concentrations of poloxamer Pluronic F127 and F68. The gelation temperature was determined by tube-reverse method. Rheological measurements were carried out to evaluate T_{s-g}, stable viscosity and gel strength. Erosion of the gels and release of dexamethasone sodium phosphate (DSP) from the gels were investigated by membrane-free method and HPLC. Increased F127 concentration in gel decreased the gelation temperature, T_{s-g} as well as erosion of the gel and drug release rate, while viscosity and gel strength rose accordingly. However, increased F68 in gel could lead to the opposite result. The poloxamer solution below T_{s-g} is Newtonian fluid with comparatively low viscosity, but shows the characteristics of the pseudoplastic fluid when temperature rises near to T_{s-g}. Drug release was controlled by the erosion of the gel matrix, and both of them followed the zero-order kinetics. An optimized formation containing 22.5% F127 and 2.5% F68 showed more desirable characteristics which meet the clinical requirements and is of potential in future clinical therapy.

Keywords: poloxamer sol-gel transition temperature gelation temperature stable viscosity elastic modulus thermosensitive *in situ* gel

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