Preparation and Quality Evaluation of Neomycin Sulfate/Dexamethasone Sodium Phosphate Thermosensitive Ophthalmic Gel

Qi ZHANG #, Yang CHEN #, Jiangbo LIU, Liya ZHOU, Lei LUO * & Yonghuang LUO *

College of Pharmaceutical Science, Southwest University, Chongqing, 400715, China

SUMMARY. Neomycin sulfate/dexamethasone sodium phosphate thermosensitive ophthalmic gels were prepared for prolonging the retention time, reducing dose frequency, and improving patient compliance. Poloxamer was the main temperature-sensitive gel base, neomycin sulfate and dexamethasone sodium phosphate were the main drugs. Then, taking the gelling temperature (Tsolv-gel), pH value, rheological property, texture property and release rate as indexes, the gel was optimized, and its quality was evaluated preliminarily. The results showed that the optimal prescription of P407 and P188 were 19 and 1% (w/w), respectively. Tsolv-gel of the samples before and after being diluted with tears was 25.6 ± 0.2 and 35.1 ± 0.1 °C, respectively. We examined the rheological characteristics of elastic modulus (G') of the prescription; the temperature before and after the dilution was 25.1 and 35.5 °C, respectively, consistent with the vial-flipping method. The release behavior of the two main drugs in artificial tears is close to first-order kinetics, and the release mechanism is based on gel dissolution and Fick’s law. The optimized prescription was selected, and the neomycin sulfate thermosensitive ophthalmic gel was prepared, which changes phase at the temperature of the human body and has a good application prospect.

KEY WORDS: dexamethasone sodium phosphate, neomycin sulfate, poloxamer, thermosensitive ophthalmic gel.

* Author to whom correspondence should be addressed. E-mail: luoyonghuang@126.com (Yonghuang Luo);
15730075066@sina.cn (Lei Luo).
# These authors contributed equally to this work.