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報告書

平成24年度「日本薬局方の試験法等に関する研究」研究報告

高分子医薬における吸入製剤の*in vitro* 吸入特性評価

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In Vitro Feasibility Study of Nebulization of High-Molecular-Weight Drugs for Pulmonary Therapy

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Summary

The aim of this study was to investigate the feasibility of nebulizing solutions of high-molecular-weight drugs (such as nucleic acid-based medicines) for pulmonary delivery. Nebulizers based on different principles were examined and the effect of polymer concentration on inhalation-related properties such as aerodynamic particle size was investigated. Low-molecular-weight DNA from salmon sperm (sDNA), polyvinyl alcohol (PVA) and fluorescein isothiocyanate-dextran (FD) were used as model drugs. Three nebulizers utilizing different principles, i.e., ultrasonic, air-jet, and vibrating mesh nebulizers, were compared. Aerosols obtained with these different nebulizers at various polymer concentrations were evaluated with an aerodynamic particle sizer based on the time-of-flight principle. The particle sizes of polymer-containing droplets from the vibrating mesh nebulizer tended to decrease with increasing polymer concentration. The relationship between aerosol droplet size and polymer concentration in the solution was confirmed by measurements of contact angle and surface tension of droplets.

Key words

Inhalation, Nebulizer, Nucleic acid medicine, Aerodynamic particle size, Contact angle