

平成 20 年度「日本薬局方の試験法に関する研究」研究報告^{*6} 日本薬局方一般試験法収載へ向けた SDS-PAGE 法及び キャピラリー電気泳動法に関する研究

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Investigational Testing of SDS-PAGE and Capillary Electrophoresis
for Biological Therapeutics, Aimed for Listing on Japanese Pharmacopeia
as General Tests

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Summary

Biological therapeutics, such as hormones, enzymes, cytokines, antibodies, blood coagulation factors and vaccines, have been attracting much attention from the pharmaceutical industry, and the development of such products has been accelerating. Among them, antibody products, used as biological therapeutics, have been growing most rapidly. In this study, the performance of SDS-PAGE and capillary electrophoresis was investigated using commercially available antibody pharmaceuticals (tocilizumab, bevacizumab, rituximab and trastuzumab), in terms of the precision, linearity and the detection capability of degradation products. Capillary zone electrophoresis (CZE) showed the highest precision for peak areas and migration times, and analysis could be completed within 10 min, which is much faster than in the cases of SDS-PAGE and capillary gel electrophoresis (CGE). All the methods examined in this study gave a good linear relationship between sample concentration (sample dose) and band/peak area. As for detection capability of degradation products, good results were obtained with CGE. However, pressure injection was found to be problematic; because of the difficulties of sample injection into a capillary filled with a high-viscosity running buffer, as is often used in CGE, the variability of sample injection should be evaluated in advance. Furthermore, it is necessary to improve the sample preparation methods and the estimation methods for molecular weight under non-reducing conditions. Therefore, further investigation is necessary to develop and extend the versatility of testing methods for biological therapeutics.

Key words

SDS-PAGE, Capillary electrophoresis, Antibody, Biological therapeutics, Tocilizumab, Bevacizumab, Rituximab, Trastuzumab