財団 Information ▶報告書

令和２年度「日本薬局方の試験法等に関する研究」研究報告
吸入剤における Time-of-Flight の原理に基づく簡便な空気力学的粒度測定法に関する検討
―多孔性粒子から構成される吸入剤への適用*2

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Simple Method to Measure the Aerodynamic Particle Size Distribution Based on the Time-of-Flight; Application to Inhalation Composed of Porous Particles *2

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Summary

There is a need to include a general test method in JP that can quickly measure inhalation characteristics for process control and quality control at the manufacturing sites of pharmaceutical companies. However, at present, it is difficult to measure a sample quickly by means of the aerodynamic particle size measurement method listed in JP. Furthermore, although it is expected that inhalations having porous particles will be put on the market, a simple method to measure aerodynamic particle size for evaluation of the inhalation characteristics has not been established. Therefore, the purpose of this study is to obtain basic information for establishing a simple method for DPI to measure aerodynamic particle size distribution, which is correlated with the results of inhalation characteristic tests of JP. A dispersion attachment was added to an aerodynamic particle sizer (APS) so that formulations could be dispersed under the same conditions as used for the multi-stage liquid impinger (MSLI). Then, we examined the correlation between MSLI and APS using lyophilizate for DPI formulations that generate porous particles on inhalation. It is difficult to accurately determine the aerodynamic particle size distribution of porous particles by APS due to the difficulty in estimating the particle density. However, there was a significant correlation ($r = 0.9962$, $p = 0.0002$) between MSLI and APS results when the particle density settings for APS measurement was calculated by using a conversion factor of 3.75, based on the result of MSLI. A large number of samples can be measured in a short time by using APS with a dispersion attachment and this conversion factor, thereby enabling more efficient optimization of dry powder inhalers.

Key words

Dry powder inhalation, Aerodynamic particle size distribution, Time-of-flight measurement, Porous particles