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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*2
バイオ医薬品の凝集体試験方法等に関する研究

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Current Status of Aggregation Test Methods for Biotechnology-derived Drugs

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Summary

Formation of aggregates continues to be one of the major quality concerns in development of biotechnology-derived drugs, because the presence of large quantities of aggregates is believed to cause undesirable immunogenic responses. Aggregates with a wide range of sizes and shapes can be formed, and comprehensive characterization of the aggregates in biotechnology-derived drugs continues to be challenging. In particular, aggregates ranging in size from 40 nm to 10 μm are attracting attention from regulatory authorities, industry and academia, because aggregates in this size range are not practically defined in the specification tests. This report reviews the current status of methods for analysis of protein aggregates, including emerging ones, and discusses an opinion put forward by an FDA member about the necessity for analysis of aggregates in relation to immunogenic potential.

Key words

Aggregates, Sub-visible particles, Immunogenicity, Biotechnology-derived drugs, Analytical methods