

質量分析を用いたペプチド及びたん白質性医薬品の確認試験法に関する研究**

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Study of Mass Spectrometry as an Identification Test for Peptide/Protein Products

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Summary

Since mass spectrometry (MS) and tandem mass spectrometry (MS/MS) make it possible to measure accurately the mass of peptides and proteins and provide structural information, they have been used for not only analysis of primary structure and post-translational modification but also identification tests of peptide and protein products. However, assay methods for identification tests have not been fully standardized due to the availability of different ionization methods, many types of analyzers and various analytical conditions. In this paper, mass spectrometry for identification tests of peptide and protein products has been standardized and validated in a collaborative study using several types of mass spectrometers equipped with ESI or MALDI sources. Based on the results of molecular mass measurement from the collaborative study, we propose the following acceptance criteria: i) 0.3 Da (monoisotopic mass) for peptides with masses of <1,000 Da, ii) 300 ppm (monoisotopic mass) and 500 ppm (average mass) for peptides with masses of 1,000~6,000 by ESI-MS and MALDI-MS, and iii) 500 ppm and 1,600 ppm (average mass) for proteins with masses of 6,000~22,000 Da by ESI-MS and MALDI-MS, respectively. Although peptides with masses of 1,000~4,000 Da yielded 5~10 b- and y- series fragments by CID-MS/MS and PSD, the detected ions were not identical among laboratories. Further study is necessary for optimization and standardization of MS/MS conditions.

Key words

Mass spectrometry, Tandem mass spectrometry, Peptide, Protein, Biologicals, Identification test