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ペプチドマップ法の国際調和に関する研究*3

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Progress in International Harmonization of Pharmacopoeial Requirements for
Peptide Mapping of Biotechnology-derived Protein Pharmaceuticals

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Summary

Peptide mapping is an analytical technique used for protein identification and characterization. It provides information on the primary structure and modifications of a protein by analyzing a set of peptides obtained by selective cleavage of the protein. A harmonized text on peptide mapping was included as general information in Supplement II to the Japanese Pharmacopoeia 14th edition in 2005. However, due to advances in analytical technology, revision is in progress with USP as the coordinating Pharmacopoeia. Here, we discuss intended use, system suitability and acceptance criteria. We suggest that it is important to define the objective of peptide mapping in the context of an overall quality control strategy.

Key words

Peptide mapping, International harmonization, System suitability