

宿主細胞由来タンパク質の試験法に関する研究*²

日向 昌司, 多田 稔, 橋井 則貴, 石井 明子*¹

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Study on Assay of Host Cell Proteins (HCPs) Present as Impurities in Biopharmaceuticals

Masashi HYUGA, Minoru TADA, Noritaka HASHII and Akiko ISHII-WATABE*¹

Summary

Host cell proteins (HCPs) are process-related impurities that may be present as contaminants in biopharmaceuticals. A major safety concern is that HCPs not only induce anti-HCP antibodies, but may also act as adjuvants to promote the development of anti-drug antibodies. To evaluate the amount of residual HCPs, it is important to establish a suitable purity test of the drug substance or its intermediates. Sandwich immunoassay (e.g. enzyme-linked immunosorbent assay; ELISA), a highly sensitive and specific quantitation assay, has frequently been used for the assay of residual HCPs. But, since HCPs are a mixture of various proteins, there are many issues to consider in the establishment of a quantitative assay for HCPs using sandwich immunoassay. Recently, the US Pharmacopoeia and European Pharmacopoeia have each published new chapters providing guidance on HCP assays. Here, in order to provide a basis for drafting Japanese Pharmacopoeia general information for HCP assays, we assess the key points required for the development of suitable HCP assays, with reference to the other two Pharmacopoeias.

Key words

Host cell proteins, Biopharmaceuticals, HCP assay, Process-related impurities, Pharmacopoeia