Development of an Enzyme-Linked Immunosorbent Assay Method for Residual Host Cell Protein in Recombinant Anti GPⅡbⅢa antibody

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The purpose of this study is to develop a measure system of host cell-derived residual protein in final pharmaceutical product. The host cell proteins(HCPs) measuring is very important test item in pharmaceutical qualification control. Because the HCP can occur various kinds of side effect to product, when the HCP remains in final product. Commercial reagents and generic analytical methods are available for quantification most of the these contaminants. However, no generic assay is available for quantification of the specific contaminant HCPs which are unique to a novel purification process. The quantification of residual HCPs in recombinant anti GPⅡbⅢa antibody (ISU301) were developed using a process-specific immunoligand assay which was based on the enzyme linked immunosorbent assay (ELISA) system. The developed ELISA system was used to measure HCPs in ISU301 and validation of HCPs in purification process. The practical implication of these results is that the developed ELISA system can be used for HCPs qualification control and this system will be applicable to develop another ELISA system of different antibody drug.

References

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