

Analysis for Residual Host Cell Proteins in Process Streams of Recombinant Anti GPIIb/IIIa Antibody

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Analyses of crude samples from biotechnology processes are often required in order to demonstrate that residual host cell impurities are reduced or eliminated during purification. The purpose of this study is to develop a measure system of host cell-derived residual protein in final pharmaceutical products. Commercial reagents and generic analytical methods are available for quantification most of these contaminants. However, no generic assay is available for quantification of the specific contaminant which are unique to a novel purification process. The quantification of residual HCPs in recombinant anti GP II b/III a antibody (ISU301) was developed using a process-specific immunoligand assay. The assay was based upon use of rabbit polyclonal antibodies raised against CHO host cell proteins from null cell, extracted by same manufacturing process used to produce ISU301. We made validation report following categories : quantification limit, specificity, precision (reproducibility, intermediate precision), linearity, range and accuracy as described in the ICH guideline. The results showed that this system can be applied for another recombinant protein production process.

References

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