Validation of an ELISA method for the detection of anti-host cell antibodies in human serum

Aim of the study

Biopharmaceutical products may contain host cell derived protein impurities at low levels. A method for the detection of antibodies to HCP in human serum of patients treated with recombinant drug protein was validated for immunogenicity assessment.

Analyte

Anti-host cell antibodies.

Methodology

The ELISA method consists in a direct ELISA using antigen-coated microwell plates, while the detection system is a mixture of commercial HRP conjugated antibodies. Positive samples are confirmed by titration and specificity tests. The ELISA method was tested for sensitivity, specificity, intra- and inter-run accuracy and precision, and for inter-operator variability using spiked quality control samples.

System

Human serum

Therapeutic area

Reproductive Medicine

Development stage

Preclinical

Customer

Large pharmaceutical company

Results

Anti-host cell antibodies can activate immunogenic reactions in treated patients. Here, an accurate, precise and selective ELISA method was validated to detect the presence of these antibodies in patient serum.

Advantage of the methodology

Anti-host cell antibodies can activate immunogenic reactions in treated patients. Here, an accurate, precise and selective ELISA method was validated to detect the presence of these antibodies in patient serum.