

Host Cell Protein Antibodies

Rockland Immunochemicals released Host Cell Protein (HCP) antibodies that detect high, medium and low molecular weight proteins. Host Cell Proteins are process-related impurities derived from a host cell expression system that may be present in trace amounts in a final drug substance. HCP antibodies are used to detect impurities in biologically-based therapeutics. Assays are further developed using custom-manufactured process specific antibodies. The FDA requires that pharmaceutical and biotechnology companies producing therapeutic antibodies minimize HCP contamination to an acceptable level. Failure to identify and sufficiently remove contaminants early in drug development can result in reduced drug efficacy or adverse toxic or immunological reactions in patients.

ELISA, the most widely used assay for determining the presence of HCPs, uses a polyclonal antibody mixture raised against host cell proteins. The accepted workflow for evaluating the immunocoverage of HCP antibodies involves 2-D gel electrophoresis followed by Western blotting. Rockland now provides Bioprocessing researchers with antibodies and custom HCP assay development services that streamlines and regulates this workflow.

Rockland Immunochemicals, Inc., 800-656-7625, www.rockland-inc.com/hcp.aspx [1]

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Links:

[1] <http://www.rockland-inc.com/hcp.aspx>