

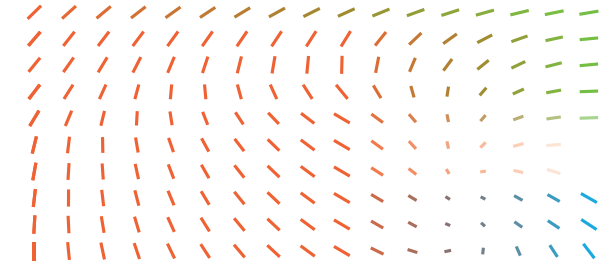
Your Guide to Host Cell Protein Analysis

Host Cell Proteins (HCPs) are low-level process-related impurities that can significantly affect drug efficacy and potentially cause immunogenicity. Therefore, HCPs are regarded as a critical quality attribute (CQA) in biopharmaceuticals. Identification and quantification of residual HCPs are critical for biopharmaceutical companies to be in accordance with regulatory agency guidelines (ICH Q6B).

Product Purity



Typical Questions in Biopharmaceutical Development	Suitable Methods at ProtaGene	Expected Outcomes
Can I characterize the HCP impurity clearance across manufacturing process steps?	<ul style="list-style-type: none"> • Mass Spec. (Identification) • 2D-Page 	<ul style="list-style-type: none"> • Detailed list of identified HCPs • Sample comparison • HCP intensity (Abundance) • Quantification (Relative or absolute) • Statistical evaluation
Are the HCP profiles between my Process or Drug Substance samples comparable?		
Can I get quantitative values of critical HCPs?	<ul style="list-style-type: none"> • Mass Spec. (Identification) • Mass Spec. (Absolute Quant. by Isotope Dilution MS) 	



Benefits of Working with ProtaGene

- ◆ Customized HCP Project Design according to your needs
- ◆ More than 70 different HCP projects successfully run during the last 5 years
- ◆ Projects for NBE, Biosimilars, Vaccines, and Gene Therapy Products
- ◆ Hosts include CHO, *E.coli*, yeast, HEK293, Sf9, plant-based platforms and others
- ◆ Successful support for IND/IMPd & BLA/MAA submissions

ELISA Suitability



Typical Questions in Biopharmaceutical Development	Suitable Methods at ProtaGene	Expected Outcomes
Does my ELISA cover all HCP impurities, in particular potential critical HCPs?	<ul style="list-style-type: none"> • Mass Spec. (IAC-MS) • 2D-Page + Western blot 	<ul style="list-style-type: none"> • Coverage value (Covered and non-covered HCPs) • Detailed list of identified HCPs • Sample comparison • Spot quantification • Spot identification via LC-MS
Coverage/specificity of different ELISA Kits using different anti-HCP antibodies?		