



CAPRION

Accelerating Precision Medicine

HOST CELL PROTEIN ANALYSIS USING HCP DETECT™

IMPROVE YOUR RISK CONTROL STRATEGY

No other solution provides a more sensitive, specific and gel-free solution to detect, quantify and monitor low abundance host cell proteins (HCP) than ProteoCarta™ mass spectrometry-based platform technique.

→ PROTECT YOUR PRODUCT AND YOUR BOTTOM LINE.

Detecting residual host cell proteins (HCPs) is critical to drug safety, efficacy and regulatory qualification. Incomplete detection of HCPs in biopharmaceuticals development can lead to product degradation, product instability and adverse immunogenic reactions in patients. As regulatory authorities recommend monitoring and removal guidelines, there's never been a better time for a more reliable solution, HCP Detect™.

→ YOUR PRODUCT DESERVES A BETTER HCP SOLUTION.

Although immunoassays, such as ELISA remain the gold standard, the presence of low levels of HCP requires a more sensitive method of detection. Immunoassays often don't have the resolution to separate and detect individual HCPs.

→ IMPROVE RISK CONTROL WITH HCP DETECT™.

Caprion's state-of-the-art ProteoCarta™ mass spectrometry-based platform along with our unique HCP Detect™ solution addresses the limitations of immunoassays. Our solution provides an orthogonal method for the identification and quantitation of all types of process samples through all phases of biologics and biosimilar manufacturing to improve your risk control strategy.

HCP DETECTION AS LOW AS 1 PPM

With detection limits as low as 1 ppm per drug sample, HCP Detect™ is one of the most sensitive methods that provides a complete analysis of your product purity.

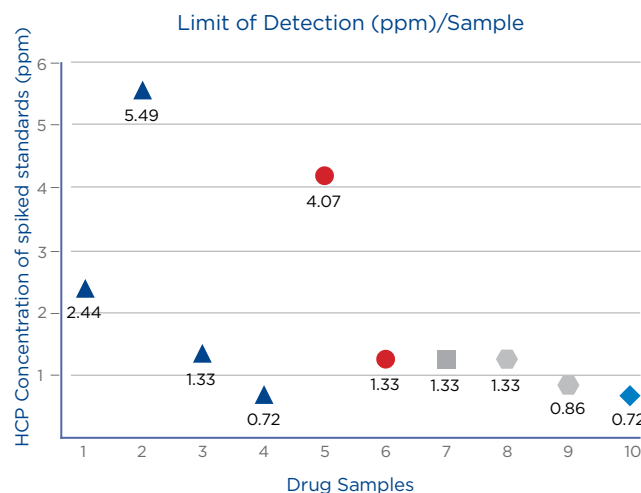


Figure 1: Example of 10 drug substances from three different production systems.

CHO - mAb ▲
 rCHO ●
 E.Coli - Peptide ■
 E.Coli - Recombinant protein ◊
 Human - Recombinant protein ◆



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HCP DETECT™

HCP IDENTIFICATION

Based on in-solution digestion followed by in-depth peptide analysis with LC-MS/MS.

- Unbiased (label-free, gel-free)
- High sensitivity, reproducibility
- Extensive coverage using proprietary datamining tools paired to multiple protein search
- Confident protein assignments and abundance
- Simple conversion to a quantitative multiplexed assay

HCP QUANTITATION, TARGETED MRM

Rapid confirmation and absolute quantitation of individual HCP using highly specific and sensitive multiplexed MRM panels (LC-MRM/MS).

- 10 or more known HCPs in absolute quantitation, 100 or more in relative quantitation, all in one single assay
- Stable isotope labeled (SIL) peptides for internal standards
- Precise and accurate results in ppm with precision report
- Standard curves and QC samples included

RELATED SERVICES

Caprion, offers a fully integrated bioanalytical platform with an extensive suite of complementary assays.

PROTEOCARTA™ Mass Spectrometry

- Pharmacokinetics (PK)
- Intact Mass
- Biomarker Quantitation

IMMUNECARTA® Immune Monitoring

- Pharmacodynamics (PD)
- MSD (Cytokine Analysis)
- Receptor Occupancy

OUR EXPERIENCE. YOUR SCIENCE.

- More than 20 years of biomarker discovery expertise
- A leader in complex bioassay development and testing
- State-of-the-art facility, GLP/GCLP/GMP compliant
- Comprehensive bioinformatics solutions and proprietary analytics tools

Caprion Biosciences is a leading contract research laboratory providing state-of-the-art integrated platforms in proteomics and immune monitoring to the pharmaceutical and biotechnology industry.

For more information:
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