HCP DETECT™

Identification and Monitoring of Problematic HCPs for Improved Process Development

CellCarta

formerly
Caprion-HistoGeneX

CASE STUDY

MAPPING PRECISION MEDICINE

SITUATION

A leading biotech detected product instability due to problematic HCPs

During stability testing, our client detected product instability due to polysorbate degradation and the co-purification of host cell lipases was suspected. Although the drug substance (DS) lot had met the target specifications for HCP purification, the multianalyte ELISAs used for HCP testing provided only an aggregate readout of residual HCPs. An orthogonal technology was needed to identify the specific HCPs present in the final DS and to track clearance in the process intermediates.

CHALLENGE

Provide a reliable, comprehensive inventory of residual HCP in the client's process intermediates and final DS

- HCP ELISAs, often used in process development, do not provide information on individual HCPs.
- Relying exclusively on antibody-based methods can also lead to under- or overestimation of total HCP levels.

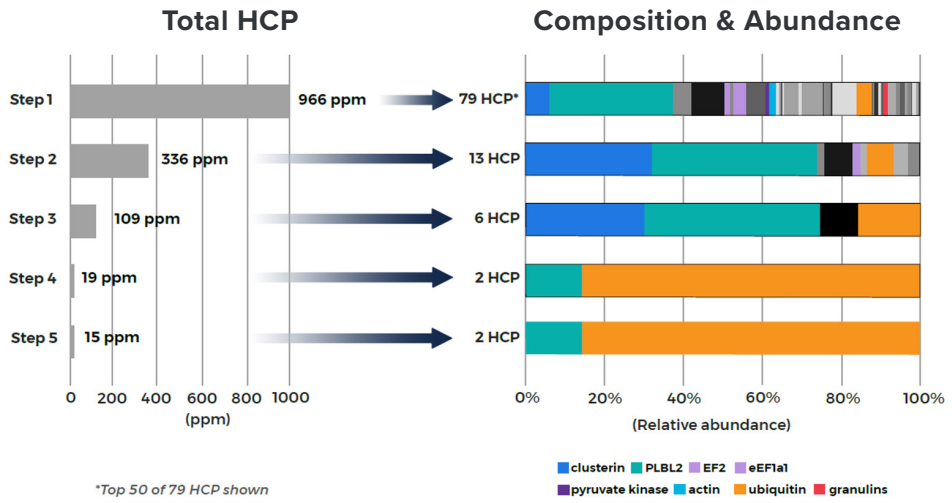
SOLUTION

LC-MS/MS assays identified problematic HCPs in the final DS, including lipases

LC-MS/MS was used as an orthogonal method to provide confirmatory and supplemental data on the identity and number of HCPs, and their relative abundance in ppm.

- No prior knowledge of HCP content or development time was needed to initiate the analysis.
- State-of-the-art LC-MS/MS was used to measure HCPs in an initial set of study samples, with an assay sensitivity down to 10 ppm per individual HCP.
- For HCP identification, data was searched against a custom process-specific database containing the entire host cell proteome, and the relative abundance of each identified HCP was determined using spectral count-based algorithms.

The use of LC-MS/MS to track total and individual HCPs to assess purification provided the client with actionable data for optimization of the chromatography steps.



OUTCOME

Improved purification process that removed problematics HCPs

The LC-MS/MS analysis of a subsequent set of study samples from the client's improved manufacturing process showed improved purification efficiency and clearance of the lipase. Using HCP data from CellCarta, the client was able to optimize the purification process for maximal API and yield, while reducing specific HCPs of concern.

Early use of LC-MS/MS as an orthogonal method for HCP monitoring can identify areas for process improvement monitoring and control.

CellCarta

formerly
Caprion-HistoGeneX

ABOUT CELLCARTA

Leading provider of specialized precision medicine laboratory services to the biopharmaceutical industry. Leveraging its integrated analytical platforms in immunology, histopathology, proteomics and genomics, as well as related specimen collection and logistics services, CellCarta supports the entire drug development cycle, from discovery to late-stage clinical trials. The company operates globally with over 700 employees in its nine facilities located in Canada, USA, Belgium, Australia, and China.

For more information on how CellCarta can partner with you, please contact us:

www.cellcarta.com
info@caprion.com
Toll Free: + 1 877 776 3443

HEADQUARTERS

141 President-Kennedy Avenue, Suite 5650
Montreal, Quebec, Canada H2X 1Y4
Phone: + 1 514 360 3600