



# Top 20 Host Cell Proteins

– including 4 of potential concern –  
found in commercial monoclonal antibodies

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# Are ELISAs informative enough?

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## **Protein impurities in monoclonal antibodies**

Monoclonal antibody (mAb) drugs are often administered in high doses and multiple times. Host Cell Protein (HCP) impurities are therefore of high importance for patient safety, since some may cause – unwanted - immune responses. Other HCPs may result in degradation, introduce modifications, and/or loss of drug activity.

HCP ELISAs usually find that mAbs are very clean. But there is no guarantee that ELISAs cover all impurities – and they give no information about individual HCPs. Thus, you risk that problematic HCPs go unnoticed.

Mass spectrometry (LC-MS) analysis, on the other hand, provides you with a tool to analyze individual HCPs - and spot problematic ones early on.

# TOP 20 HCPs found in commercial mAbs

Name of Host Cell protein	Comments*
Fructose-bisphosphate aldolase A	
Palmitoyl-protein thioesterase 1	
Peroxiredoxin-1	
Lysosomal protective protein	
<b>Clusterin</b>	← Problematic?
Immunoglobulin G-binding protein A	
Cornifin-A	
Alpha-galactosidase	
Acid ceramidase	
Peroxiredoxin-2	
Thioredoxin (Trx)	
Galectin	
<b>Peroxiredoxin-4</b>	← Problematic?
<b>Endoplasmic reticulum chaperone BiP</b>	← Problematic?
Glutathione S-transferase	
Microtubule-associated proteins 1A/1B light chain 3A	
<b>Cathepsin L1</b>	← Problematic?
Inter-alpha-trypsin inhibitor heavy chain H5	
Phosphoglycerate kinase	
Roundabout-like 2	

\* Clusterin and BiP may cause immunologic reactions, Peroxiredoxins are suspected of different reactions including tween degradation, and Cathepsin L is a protease that can degrade the mAbs

# How did we do it?

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## **Comparing Host Cell Protein profiles of commercial monoclonal antibodies**

For more than 5 years, Alphalyse has studied Host Cell Protein impurities in monoclonal antibodies (mAbs) with mass spectrometry (LC-MS) analysis.

Through LC-MS analysis we have a tool to compare individual HCP impurities between mAbs. This is not possible with HCP ELISAs which are specific for each mAb product.

For this study, Alphalyse thus used LC-MS to analyze and compare the HCP profiles of 16 commercial mAbs and biosimilars.

# Commercial mAbs analyzed

Drug	Commercial name	Host
Bevacizumab	Avastin	CHO
Secukinumab	Cosentyx	CHO
Ramucirumab	Cyramza	Mouse
Cetuximab	Erbix	Mouse
Obinutuzumab	Gazyvaro	CHO
Adalimumab	Humira	CHO
Rituximab (rituxan)	Mabthera	CHO
Nivolumab	Opdivo	CHO
Tocilizumab	RoActemra	CHO
Infliximab	Remicade	Mouse
Infliximab	Remicade	Mouse
Infliximab	Remicade	Mouse
Infliximab	Remicade	Mouse
Infliximab	Remicade	Mouse
Infliximab	Inflectra	Mouse
Infliximab	Flixabi	Mouse

# Curious to learn more?

## 30 minute webinar: Comparison of HCP profiles in monoclonal antibodies

Would you like know which Host Cell Proteins (HCPs) were found in which mAb – and in which amount?

We prepared a 30-minute webinar in which you can learn more about the LC-MS analysis of HCPs.

You will receive an invitation by email soon – we hope to see you there.

