ALPHALYSE™

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Mass spectrometry-based HCP analysis

Identity and quantity of each Host Cell Protein and total HCP content in ng/mg

LC-MS provides the missing details

HCP-ELISAs do not provide details about the individual HCPs in your samples – and product specific ELISAs take a long time to set up.

Mass spectrometry-based HCP analysis gives you a list of individual HCPs and their quantity. The method is applicable for all process steps from harvest sample to final drug substance.

Our platform workflow is very advantageous for purified mAbs - the detection limit is < 1 ppm - as well as small proteins, where ELISA may underestimate low Mw HCPs.

Benefits compared to ELISA

FASTER - No need for costly immunization or null cell line development. Can be applied directly to your samples.

ROBUST - Reproducible data is obtained by microflow LC-MS.

DETAILED - Individual HCPs are identified and listed with their pI, Mw, and quantity in ppm or ng/mg of drug substance.

Process development

When production processes change, the LC-MS assay quickly gives precise comparability information about the clearance of each HCP for each process step, pre and post change.

Risk assessment

Easily compare HCP profiles of clinical batches. Monitor individual HCPs or rule out the presence of HCPs known to cause immunogenicity, adjuvant effects, or reduce biological activity.

Release test under GMP

Quality control of drug substance using LC-MS analysis under GMP conditions – for use as release assay for Phase I through Phase III and marketed products.

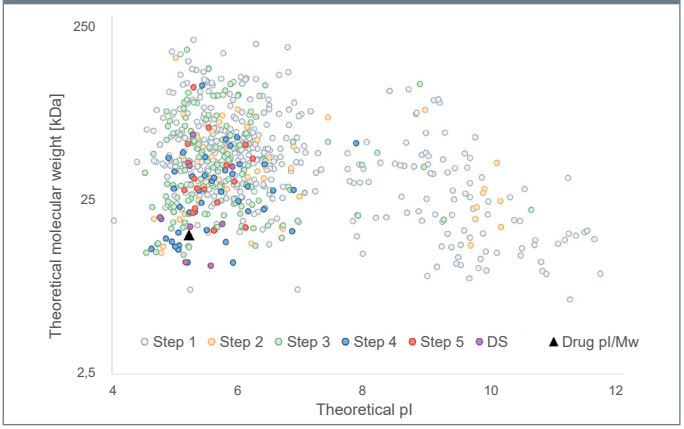
HCPs in process steps quantified by LC-MS

Host Cell Protein	Step 1	Step 2	Step 3	Step 4	Step 5	DS	Mass	pI	Protein name
sp|P0C058|IBPB_ECOLI	4,274	2,905	2,154	1 86	229	111	16,093	5.2	Small heat shock protein IbpB
sp|P0A9A9|FUR_ECOLI	158	284	296	142	147	94	16,795	5.7	Ferric uptake regulation protien
sp|P0ABK5|CYSK_ECOLI	597	913	711	618	200	68	34,490	5.8	Cysteine synthase A
sp|P69783|PTGA_ECOLI	33	250	378	256	185	62	18,251	4.7	PTS system glucose-specific EIIA component
sp|P0A8J4|YBED_ECOLI	432	215	253	222	112	21	9,827	5.5	UPF0250 protein YbeD
sp|P02930|TOLC_ECOLI	41	283	187	417	57	11	53,741	5.2	Outer membrane protein TolC
sp|P62623|ISPH_ECOLI	312	1,146	855	231	62	15	34,775	5.2	4-hydroxy-3-methylbut-2-enyl diphosphate reductase
sp|P0ADP9|YIHD_ECOLI	33	28	32	11	10	18	10,273	5.1	Protein YihD
sp|P0A763|NDK_ECOLI	106	240	100	349	113		15,463	5.6	Nucleoside diphosphate kinase
sp|P35340|AHPF_ECOLI	67	291	171	174	48		56,177	5.5	Alkyl hydroperoxide reductase subunit F
sp|P08200|IDH_ECOLI	390	271	166	355	42		45,757	5.2	Isocitrate dehydrogenase
sp|P69797|PTNAB_ECOLI	284	339	240	25	26		35,048	5.7	PTS system mannose-specific EIIAB component
sp|P0A7I7|RIBA_ECOLI	345	297	106	48	45		21,836	5.6	GTP cyclohydrolase-2
sp|P0AEN1|FRE_ECOLI	741	870	849	1,404	33		26,242	5.3	NAD(P)H-flavin reductase
sp|P36683|ACNB_ECOLI	129	87	82	9	8		93,498	5.2	Aconitate hydratase B
Number of HCPs	562	245	206	67	25	8			
Total HCP ppm (w/w)	193,169	48,548	33,391	9,599	1,493	401			
HCP % (w/w)	**19.32%**	**4.85%**	**3.34%**	**0.96%**	**0.15%**	**0.04%**			

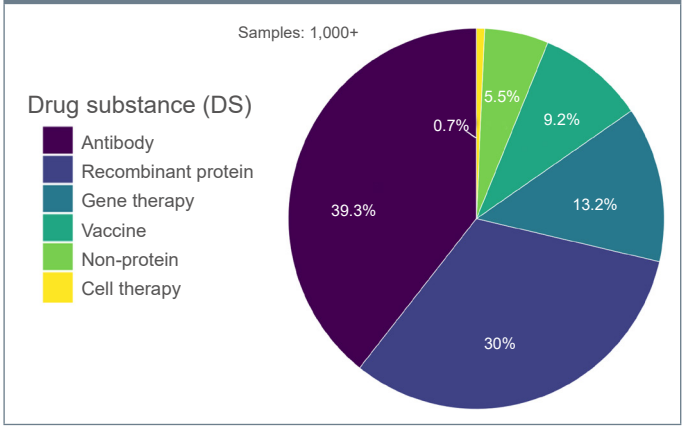
Example of results

LC-MS provides a list of the HCPs and quantities in each process step for use in process optimization and comparability.

2D plot of HCPs in each process step



Completed HCP projects by DS type



What customers say

"Targovax develops highly targeted immunotherapies for cancer patients. We used the Alphalyse LC-MS analysis as a complementary characterization method to ELISAto gain knowledge about identity and quantity of the HCPs in our adenovirus product.

Alphalyse handled the project professionally and rapidly, and we received a final report that was very well written, clearly explaining the findings."

Targovax ASA, Finland
Kristiina Hyvärinen – Director, QC

"We combined Alphalyse's LC-MS analysis with our process-specific ELISA. They provided identity and quantity of individual HCPs, allowing us to identify differences between batches.

The method is also applicable for process development – giving detailed knowledge how individual HCPs were eliminated during our downstream purification. A knowledge not obtainable from any ELISA assay."

SSI, Vaccine Development, Denmark
Max Kristiansen – Assay Development

Why work with us?

- 20+ years of experience helping biotech companies in Europe and USA
- 500+ MS-based HCP projects makes us the World's most experienced lab

Contact

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