Characterization and Comparison of Neulasta and its Biosimilar at Intact Level on a Quadrupole-Orbitrap Mass Spectrometer


ABSTRACT

Molecular weight determination of Neulasta and its biosimilar

In this study, we measured the molecular weights of Neulasta and a domestic biosimilar Neulasta is a PEGylated recombinant human granulocyte colony-stimulating factor, containing 174 amino acids (18-20 kDa) and around 20 kDa PEG chains in continuous.

For PEGylated proteins, a multiplicity of signals is generated because of the presence of ladders of multiply charged protein ions and the overlapping polydispersity of the attached PEG. This results in spectra containing overlapping signals that are difficult to deconvolute and decipher. We chose a high-resolution Orbitrap to avoid these limitations.

Hundreds of components can be baseline separated and detected with great S/N ratio in this extremely complex mixture, benefitting from our high resolution and sensitivity of the Orbitrap analyzer. (Figure 2). MS parameters are shown in Table 1-

RESULTS


TRADEMARKS/LICENSING

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