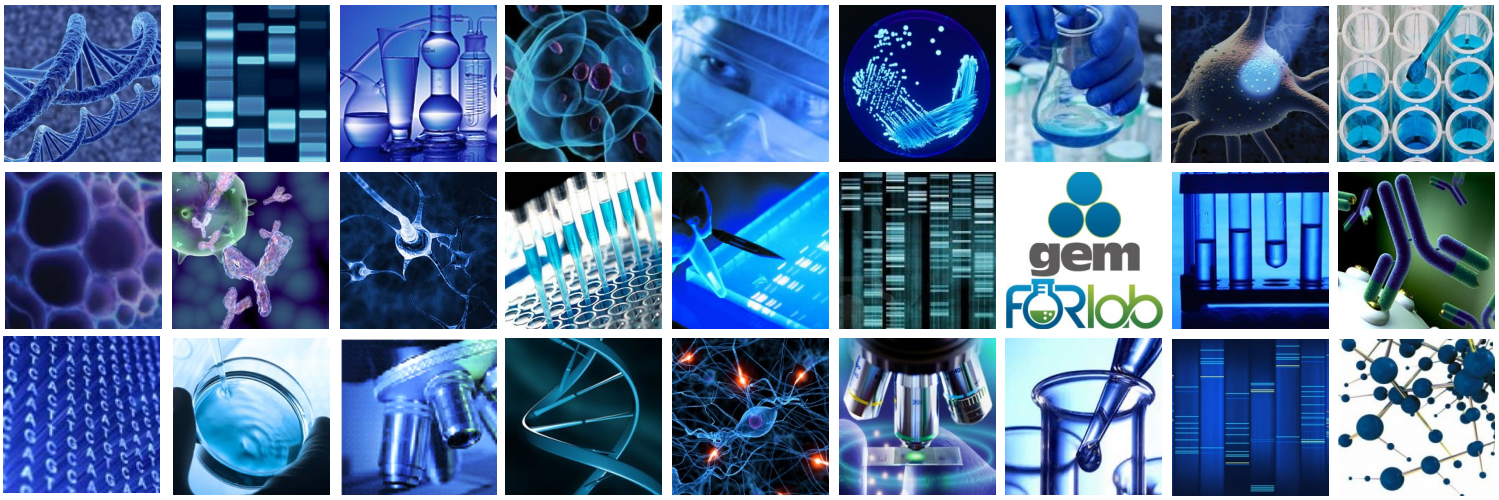

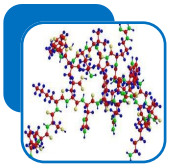

Peptide impurity characterization

Aim of the study

The characterization of impurities in production batches of a modified peptide.

Methodology

Production batches of a modified peptide were analyzed by LC-MS using a high resolution mass spectrometer, in order to calculate the exact mass of impurities.
Calculated molecular weight of impurities was compared to that of the modified peptide.

Production batches were then analyzed again by LC-MS/MS using the same high resolution mass spectrometer, in order to calculate the exact mass of fragments deriving from impurities.
Calculated masses of fragments deriving from impurities were finally compared to those of fragments obtained from the modified peptide, in order to verify if the impurities shared some fragments with the modified peptide.

Analyte A modified peptide

System Production batches

Therapeutic area Type 2 Diabete and obesity

Development stage Approved drug

Customer A multinational pharmaceutical company commercializing biological drugs nuclear medicine theragnostics.

Results

From the comparison of the exact molecular weight of the modified peptide and that of its impurities, all determined by LC-MS analyses, it was verified that most of the detected impurities derived from the loss of one or more aminoacids from the N-Terminus of the modified peptides.

These results were then confirmed by LC-MS/MS analyses: analyzing the modified peptide, more than 70 fragments deriving from its fragmentation by the high resolution mass spectrometer where assigned to the corresponding structure.

By the comparison of fragments obtained from the analysis of the impurities with those assigned to the modified peptide, it was possible to verify which portions of the latter were present in the detected impurities..

In this way, the structure of most of the impurities were determined or, at least, it was verified if they derived or not from the modified peptide and, if the case, which of its portions where conserved and which were probably modified or absent.

Advantage of the methodology

Once the fragments of the analyte are correctly assigned to the corresponding structure, it is easy and rapid to verify if detected impurities derive from that analyte and, if the case, which portions are shared among the analyte and its impurities.

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