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A validation method development on peptide mapping of monoclonal antibody drug; Trastuzumab using liquid chromatography time-of-flight mass spectrometry (LC/QTOF)

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A method for characterization on peptide mapping parameter using liquid chromatography time-of-flight mass spectrometry (LC/QTOF) have been developed and validated. Qualitative validation such as repeatability and reproducibility were performed with monoclonal antibody, Trastuzumab. The Protein Metrics software was also used for analyzing the coverage percentage of peptide mapping. The samples were prepared by reduced disulfide bond of the monoclonal antibody with dithiothreitol (DTT) and alkylated free thiol group with Iodoacetamide (IAA) then digested the peptides with restriction enzyme, trypsin, which specifically cleaves C-terminal to Arginine (R) and Lysine (K). The digestion reaction was performed at 37 ºC and incubated overnight then stop the reaction using formic acid. The liquid chromatography was performed by using C18 column and 0.1% Formic acid and 0.5% DMSO in water and 0.1% formic acid and 0.5% DMSO in acetonitrile (ACN) as mobile phases. The QTOF was operated using positive mode electrospray ionization using data dependent acquisition. The m/z were selected to second fragmentation according to priority list which generate by calculated m/z of the interested molecule. The other data acquisition processing was performed as in-house method which able to adjust to new molecules of interest. This method gives the coverage percentage over 90% in both heavy chain and light chain of the monoclonal antibody molecule. The use of LC-MSMS technique gives the highly efficient and robust approach to confirm the characteristic of the Trastuzumab molecule in peptide mapping parameter which can be updates to use with other protein molecules for further characterization.

Biography

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