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Identification and quantification of illegal peptide drugs via HILIC-DAD-MS

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Biopharmaceuticals have established themselves as highly efficient medicines, and are still one of the fastest growing parts of the health-product industry. Unfortunately, the introduction of these promising new drugs went hand in hand with the creation of a black market for illegal and counterfeit biotechnology drugs. Particularly popular are the lyophilised peptides with a molecular weight of less than 5 kDa. Most of them are meant for subcutaneous injection and are easily accessible via the internet. In recent years, different methods based on Reversed Phase Liquid Chromatography (RPLC) have been developed to detect and quantify these peptides. The emerging of more polar peptides however requires the introduction of other separation techniques. Therefore, we set out to develop and validate an analytical method based on Hydrophilic Interaction Liquid Chromatography (HILIC) to identify and quantify the most frequently encountered illegal peptides on the European market. For this objective, five different HILIC columns were selected and screened for their chromatographic performance. Among those columns, the ZIC HILIC column showed the best performance under the tested screening conditions in terms of resolution and symmetry factor for the targeted peptide set. Hence, the operational conditions were further optimised for the identification of illegal preparations via Mass Spectrometry (MS) and quantification via UV. Validation was performed via accuracy profiles based on the ISO 17025 guideline. The obtained validated HILIC-method allows for the detection and quantification of the most frequently encountered illegal peptides on the internet in a total run time of 35 minutes including post gradient equilibration and online cleaning step. Combined with a previously developed RPLC-method, the ZIC HILIC system allows for the detection and quantification of a wide spectrum of illicit peptide drugs available on the internet. Furthermore, the developed method could also be envisaged for the detection of new emerging polar peptide drugs.

Biography

Steven Janvier was a PhD-student in pharmaceutical sciences; subject: quality and risk assessment of illegal biopharmaceuticals and he done Master in bio-engineering. He Published articles in Analysis of illegal peptide drugs via HILIC-DAD-MS.

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