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Ion-pairing online UPLC-ESI-MS method for demonstrating sameness of different sulfated oligosaccharides in low-molecular weight heparin biosimilars

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Low-molecular weight heparins (LMWH) are used for the treatment of deep venous thrombosis and pulmonary embolism. Lovenox (Enoxaparin sodium) is one of several LMWHs available on the market. This drug does currently not have patent protection and as a result, several generic versions have been produced. As part of the "Abbreviated New Drug Application" (ANDA) framework, the FDA published guidelines to clarify what is required to demonstrate sameness of a generic version of Enoxaparin sodium with the innovator product, Lovenox. These guidelines include the requirement to show "equivalence of physicochemical properties". The guidelines suggest the CTA-SAX HPLC method as one method suitable to establish equivalence. In our laboratory we have used Liquid chromatography-mass spectrometry (LC-MS) as an alternative to the CTA-SAX method with several very promising advantages over it, including greater resolution and sensitivity and separation into 5-10 times the number of peaks, as well as the ability to obtain molecular weight information and identify individual components rather than providing a fingerprint only. Regular HPLC requires prohibitively long run times in order to efficiently separate the Enoxaparin oligosaccharides, but ultra-high pressure liquid chromatography (UPLC) shortens the run times to practical values. This new method can be used to quantify the percentage of saturated reducing ends, as well as the percentage of Enoxaparin chains featuring a 1, 6-anhydro structure at the reducing end. The latter quantity is a critical parameter in the characterization and biosimilarity evaluation of generic Enoxaparin samples. This methodology will allow for extremely detailed analysis of a mixture which has not been easily possible up to this point.

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Application of mass spectrometry to forensic serology for human body fluid identification

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While DNA profiling makes it possible to individualize biological stains, the unambiguous identification of the stain itself has long presented forensic serologists with a significant challenge. Current antibody and enzyme activity based assays used by forensic practitioners for biological stain identification yield only presumptive results. Positive results with non-target body, false positive results and cross-reactivity with non-human sources have all been well documented. Some tests consume unacceptable quantities of precious evidence while for other body fluids of forensic significance (e.g., vaginal fluid and menstrual blood) there are no commercial options available. These factors reduce the ability of investigators to maximize the probative potential of crime scene evidence and limit what analysts can say in court. Using proteomics-based characterization technologies, the proteomes for six human body fluids (peripheral and menstrual blood, vaginal fluid, semen, urine and saliva) have been mapped and characterized. Based on these analyses, over 30 proteins were identified as candidate high-specificity biomarkers of individual human body fluids. These candidate biomarkers included both previously described proteins such as Statherin for saliva identification, as well as many novel biomarkers such as Cornulin for vaginal fluid identification. Validation studies performed to date confirm the specificity of these biomarkers for their target body fluid and the consistency with which they can be detected across a broader human sample population. The results of these studies have identified a robust panel of confirmatory protein markers for human body fluid identification. Subsequent research and development efforts have employed targeted-ion mass spectrometry so as to leverage significant advances in proteomic technology to produce a multiplex assay suitable for the needs of forensic practitioners. A <15-minute prototype assay has been developed on a triple quadrupole mass spectrometer which processes single- and mixed-source casework-type samples (e.g., recovered from a variety of substrates and/or subjected to chemical/environmental insult) while preserving the DNA component. This offers significant advantages over existing methods; it is well suited to automated batch processing and automated data analysis while providing confirmatory stain characterization.

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