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Characterisation of Insulin Analogues

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A comprehensive physicochemical characterisation of novel biosimilar products is a prerequisite for their application and manufacturing. A side-by-side analysis, relative to reference products, can provide comparative data for biosimilars and demonstrate their suitability in relation to regulatory requirements.

The aim of this study is to determine physicochemical properties of human insulin and its two analogues, aspart and glargine. In the insulin analogues, different amino acid residues are added or substituted at certain positions along the A and B chains to give them special acting characteristics in the human body. Mass spectrometry based peptide mapping, N/C terminal sequencing and intact mass analysis were conducted to determine differences in primary structures of the insulin analogues. Disulphide bond pairing, which is critical for protein's structure and its function, was performed by online LC/ESI-MS/MS analysis. By mapping the position of each disulphide bond through sequential reduction and alkylation steps, mass spectrometry analysis eliminated downstream functional characterisation issues by confirming that the molecule is folded correctly.

Biography

Andreja Livk has over 17 years of experience in protein and peptide chemistry, including isolation and characterisation of peptides by RP-HPLC. Her skills include the synthesis of a wide range of peptides including complex bridged peptides. She has also extensively characterised low molecular mass peptides using a wide range of mass spectrometry systems, as well as de novo peptide sequencing for interpretation of MS/MS spectra.

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