ItPS Seminars

17th Nov 2023 2pm CEST

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Strategy for side reaction and impurities control in therapeutic peptide chemistry

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Comparison between the purification strategies in preparative HPLC for the purification of therapeutic peptides

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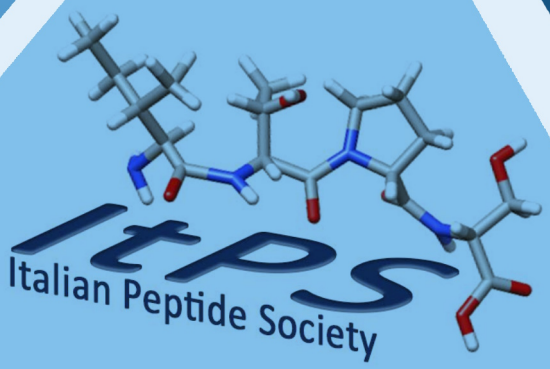
Comparison between the purification strategies in preparative HPLC for the purification of therapeutic peptides

The increased interested in therapeutic peptides generated a strong interest towards the purification procedures, particularly due to their relevant impact on the manufacturing costs. The main impurities associated with a peptide are often very similar respect to the target molecule (e.g. diastereomers), particularly if manufactured though Solid Phase Peptide Synthesis (SPPS). The current feasible approaches for their purification are related to preparative liquid chromatography, the only technique able today to reach the purity specification required by the regulatory authorities. Different approaches of chromatography at preparative scale are reviewed in this presentation, showing a case study occurred in our laboratory.



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ANDREA ORLANDIN
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Strategy for side reaction and impurities control in therapeutic peptide chemistry

Peptides drug market is a field in rapid grows in recent years. Industrial manufacturing of peptides is largely performed using the solid phase peptide synthesis approach (SPPS).
The challenge for the industry is the generation of a product at multigram to Kg scale aligned with the always more stringent market requirements in terms of quality and impurities control. Structural and stereo isomerism is a crucial step in the generation of peptide drug related impurities often very difficult to remove thought the current chromatographic techniques. In this presentation two example peptide drugs related impurities will be investigated and the trouble shooting applied to overcome their generation will be shown.

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