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Chemical degradation of proteins: Novel pathways and products probed during accelerated stability studies

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Protein pharmaceuticals are subject to a manifold of different degradation pathways. While hydrolytic pathways have been mechanistically characterized relatively well, oxidative and photolytic pathways continue to present a significant mechanistic and analytical problem. Chief among the issues encountered during oxidative and photolytic degradation are the continuing discovery of novel oxidation products and oxidation mechanisms. To this end a database summarizing all the potential oxidative and photolytic degradation products of protein pharmaceuticals would be useful to the analytical chemist charged with the characterization of protein pharmaceuticals. In this lecture, we present mechanistic and case studies on the characterization of novel degradation products, their formation mechanisms under accelerated stability studies as well as ambient conditions, and their generation on specific protein pharmaceuticals such as insulin, parathyroid hormone, human growth hormone, IgG1 and IgG2. Specifically for a series of Phe and Tyr oxidation products we have designed a fluorogenic tagging methodology, which allows rapid screening for such modifications.

Biography

Christian Schoneich is the *Takeru Higuchi Distinguished Professor* and Chair in the Department of Pharmaceutical Chemistry at The University of Kansas. He received his PhD in Chemistry in 1990 from the Technical University Berlin, Germany. Between 1987 and 1991 he worked in the Department of Radiation Chemistry at the Hahn-Meitner Institute in Berlin, Germany. In 1991, he joined the Department of Pharmaceutical Chemistry at The University of Kansas, first as a Post-doctoral Researcher and subsequently as a Faculty member. His research focuses on oxidation reactions of peptides and proteins in vivo and *in vitro*, and their potential consequences for the development of stable protein pharmaceuticals, biological aging and age-related pathologies. He has published >200 papers in the field of peptide and protein oxidation reactions.

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