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Liquid chromatography-multi stage high resolution mass spectrometry and *ab initio* studies to characterize new anticoagulants major photodegradation pathways

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The liability of a drug substance or drug product to degrade upon light exposure is well established as a common degradation cause. For this reason, the drug manufacturer provides guidelines for storage and administration of the formulations containing drugs prone to react upon light exposure. However, in some situations, these recommendations are not followed in that storage and in-use conditions do not always comply with the conditions within which it has been shown that the drug is stable. Drug substances are more amenable to degrade upon light exposure in liquid preparations than in solid formulations. Accordingly, there is a need to assess whether special procedures could be implemented to prevent any loss of drug potency and formation of photoproducts potentially harmful to the patient during the handling and administration of a liquid drug formulation. Comprehensive knowledge of mechanisms that cause drug photodegradation is therefore an inseparable prerequisite. This work aims at investigating the photodegradation behavior of two new anticoagulants drug, dabigatran etexilate and argatroban. To that end, an approach combining a computational method based upon the density functional theory (DFT) and experimental studies using liquid chromatography-high resolution multistage mass spectrometry (LC-HRMSn) was implemented. The results experimentally obtained through photoproducts identification were supported by DFT results. Structural elucidation of photoproducts along with DFT energy and geometry calculations enabled to understand process and species that initiated and propagated photodegradation. As a result, measures to improve the photostability of those drugs are proposed.

Biography

Philippe-Henri Secretan has completed his PharmD from Paris Descartes University. He is currently a third year PhD student at the University Paris Sud focusing on Drug Intrinsic Stability and Drug/Polymer Interactions. He has published more than 5 papers in reputed journals.

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