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# Liquid chromatography–multi stage high-resolution mass spectrometry to identify new anticoagulant major degradation pathways

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As the active pharmaceutical ingredient (API) may undergo degradation, leading to the drug activity loss or to occurrence of adverse effects associated with degradation products, thorough knowledge of API's stability profile is required. Liquid chromatography coupled to multi stage high-resolution mass spectrometry has shown suitable for the characterization of drugs degradation pathways. Such an approach has been successfully applied to the study of the behaviour of a new anticoagulant in the presence of various stress conditions. Dabigatranetexilate (DABET) is an oral direct thrombin inhibitor that has been approved for the prevention of blood clot formation. Since very few studies have been reported on the drug stability profile, a study related to DABET's behaviour under stress conditions was carried out in order to identify its major degradation pathways. DABET was subjected to hydrolytic (acidic and alkaline), oxidative, photolytic and thermal stress, as per ICH-specified conditions. The degradation products formed were separated by liquid chromatography (LC) using Kinetex™ 2.6 µm C18 100 A°, 50 x 2.1 mm LC column and multistage gradient mobile phase composed of water and methanol. Upto ten degradation products along with dabigatran, the active metabolite of DABET, were detected and characterized by studying their fragmentation patterns in high-resolution mass spectrometry. Under hydrolytic stress conditions, O-dealkylation may occur and formation of benzimidic acid derivatives was also observed. DABET was shown much less susceptible to photolysis and oxidative stress, even if N-dealkylation was highlighted. In view of the structures identified, various degradation pathways of DABET have been proposed.

## Biography

Bernard Do has completed his PhD at the age of 29 years from Paris-Descartes University (France). He is Hospital Pharmacist, Associate Professor and Senior Researcher of a research team focusing on drug intrinsic stability and drug/polymer interactions, at Assistance Publique-Hôpitaux de Paris and Paris-Saclay University. He has published more than 40 papers in reputed journals and serving as an Editorial Board Member of repute.

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