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Determination of Ticagrelor chemical stability and characterization of its degradants

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Ticagrelor is a direct-acting and reversible P2Y12-adenosine diphosphate (ADP) receptor blocker used as antiplatelet drug. The drug was subjected to force degradation studies under several stress media. The degradation products generated have been detected and identified by high-pressure liquid chromatography multistage mass spectrometry (LC-MSn) along with high-resolution mass spectrometry. C18 XTerra MS column combined with a linear gradient mobile phase composed of a mixture of 10 mM acetate ammonium/ acetonitrile was shown suitable for drug and impurity determinations and validated as a stability indicating method. Structural elucidation of the degradation products relied on MSn studies and accurate mass measurements giving access to elemental compositions. Up to nine degradation products resulting from oxidation/ autooxidation, S-dealkylation and N-dealkylation have been identified, covering a range of possible degradation pathways for derivatives with such functional groups. Kinetics was also studied in order to assess the molecule's shelf-life and to identify the most important degradation factors. Eventually, an in silico toxicological study was undertaken starting from the structure of the degradation products in order to know any potential risk resulting from drug degradation.

Biography

Hassane Sadou Yaye completed his Pharma D and, he is head of the laboratory of quality control of pharmaceuticals in the department of Pharmacy (Pitie-Salpêtriere hospital - Paris); and PhD student (University Paris Sud). His research focuses on APIs intrinsic stability studies which include the structure elucidation and the main routes of their degradation.

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