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A review of selected bioanalytical methods for bioavailability and bioequivalence studies of pharmaceuticals

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This paper reviews selected bioanalytical methods used for the analysis of new molecular entities (NMEs) approved by the FDA. It will include the antiretroviral drugs, atazanavir, indinavir and emtricitabine, the antibacterial gemifloxacin, the cholesterol-lowing rosuvastatine, the anti-cancer drug gefitinib and aprepitant for neurological disorders. Electrospray ionisation-quadrupole ion trap mass spectrometry (ESI-MS^n) is employed to generate tandem mass spectrometric (MS^2) data of the drugs studied and structural assignments of product ions are supported by quadrupole time-of-flight mass spectrometry (QToF-MS/MS). These fragmentation studies are then utilised in the development and validation of a specific and sensitive liquid chromatographic method (LC-ESI-MS^2) to identify and determine these drugs at therapeutic concentration levels in serum after a single protein precipitation procedure with acetonitrile. In addition, this method is compared to the application of gas liquid chromatography-flame ionisation detection (GLC-FID) and differential pulse polarography (DPP) for the analysis of these NMEs in serum.

Biography

Emeritus Professor WF Smyth has published 145 full papers, several short papers and 20 reviews. He has written two books "Voltammetric Determination of Molecules of Biological Significance" and "Analytical Chemistry of Complex Matrices" and is currently researching LC-MS for drug/metabolite and natural product analysis.

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