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Addressing biosimilars: A future perspective

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Biopharmaceuticals represent a fast-growing and important class of drugs for the treatment of various severe diseases like growth disorders, acute myocardial infraction, leukemia, neutropenia, ischemic events etc. "Biosimilars" (in Europe) or "follow-on biologic" (in US) are basically protein molecules which are similar, but not identical to, an existing available approved product. In contrast to available generic drug, it is next to impossible to create copycat of a biological drug because of intricate nature of biological (protein) molecules.

Research also suggests that because of inactivation by the body's normal immune response, protein molecules lose their efficacy when used for longer duration or may provide a more rapid immune response than original drug; thereby results serious side effects in patients.

In addition, biosimilars have enormous regulatory issues as they are not considered to be generic drugs. In contrast to generic drugs, there is no adequate guidance available for the approval of biosimilars in regulated market which in turn provide additional advantage to innovator to survive in the market for longer period.

Compare to US regulations where there are lack of legislation for formal approval process, Europe has more conspicuous guidance on biosimilars.

Based upon above scenario there is huge expectation of industries from regulatory bodies to provide formal guidance which reduce healthcare expenditure, increase access of biological drugs to patients by considering their safety and encourage development of affordable and quality biosimilars.

By keeping above mentioned scenario in mind, authors have made an attempt to discuss following issues related to biosimilars: safety, need for clinical trials and indication specific approval, product identifiability and traceability, post-marketing risk management plans required, automatic substitution, naming and labeling/ prescription rules and how biosimilars should be evaluated by regulators, pharmacist, physicians and patients.

Development and validation of LC-MS/MS method for determination of atorvastatin and its metabolites in human plasma

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A sensitive and selective liquid chromatographic tandem mass spectrophotometric method was developed for determination of Atorvastatin and its metabolites (Ortho hydroxy Atorvastatin and Para hydroxy Atorvastatin). Atorvastatin is an antihyperlipidimic which inhibits HMG CoA reductase enzyme found in liver tissue. A simple liquid – liquid extraction using Rosuvastatin as internal standard was employed. The post treated samples were analyzed on a Thermosurveyor HPLC connected with quadrapole tandem mass spectrometer interfaced with heat electro spray ionization (HESI). The mobile phase used was acetonitrile: buffer solution (65:35%v/v). Atorvastatin, Ortho hydroxy Atorvastatin, Para hydroxy Atorvastatin and internal standard (Rosuvastatin) were detected by mass spectrometer operated in the positive MRM mode at m/z 440.4, 250.0, 440.2, and 258.0 respectively. The concentration range for Atorvastatin, Ortho hydroxy Atorvastatin and Para hydroxy Atorvastatin were found to be 0.512ng/ml to 58.481ng/ml, 0.447ng/ml to 54.465ng/ml, 0.096ng/ml to 10.957ng/ml respectively. The inter and intra day precision and accuracy showed reproducibility and good linearity (r2>0.99). Each plasma sample was chromatographed within 5 mins. The method herein described can be successfully applied for determination of Atorvastatin and its metabolites in human plasma.