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E-BABE-Encyclopedia of bioanalytical methods for bioavailability and bioequivalence studies of pharmaceuticals

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Encyclopedia of Bio analytical Methods for Bioavailability and Bioequivalence Studies of Pharmaceuticals (E-BABE). It is a unique encyclopedia involving bio analytical methods for bioavailability and bioequivalence (BA/BE) studies of pharmaceuticals for suitable method selection with thousands of combinations and searches against these methods. Most scrutinized literature was collected from different sources such as Afghanistan Pharmaceutical Directorate. The bio analytical method assessment of the studied drug product, carried out in our laboratories, covers two aspects of evaluation. The first one is the drug in-vitro evaluation including conformity of drug active ingredient content and content uniformity employing official pharmacopoeia methods, and also the determination of the drug dissolution rate in accordance with the official methods. These tests have been conducted to verify compliance of the drug product to applied quality standards. The second aspect involves biological or in vivo evaluation. This evaluation consists of microbiological assay for the label claim of the studied drug product, and development and validation of a suitable and reproducible bio analytical assay method to obtain plasma concentration-time profile. Data obtained to be employed for assessment of the drug product kinetics. Depending on the chemistry of the drug product, reversed-phase high performance liquid chromatography (RPLC) has been chosen, as the analytical technique, in developing drug assay method, due to its explosive popularity for analytical separations. This choice was also due to many factors as will follow. The variation of element composition alone extends both retention and selectivity in RPLC over an extremely broad range of analyses. Practically, all reversed phase separations are carried out on stationary phases with chemically modified hydrophobic surfaces. Minor variations in the surface chemistry and geometry can lead to noticeable differences in surface interactions and, as a result, to differences in chromatographic selectivity. Mobile phase (eluent) is by far the major "tool" for the control of analyte retention in RPLC. Variations of the eluent composition, type of organic modifier, pH, and buffer concentration provide the chromatographer with a valuable set of variables for successful development of a separation method. Mobile-phase pH affects the analyte ionization and thus its apparent hydrophobicity and retention. Most drug products may be ionizable, and therefore their retention is affected by the mobile-phase pH. The influence of temperature and type and concentration of organic analyte and pH modifier ionization are also related to HPLC retention. All the choices the biocatalyst has in terms of bonded phase, aqueous phase modifier, and organic modifier can have synergistic effects on the analyte retention and selectivity in RPLC. These parameters illustrating the power of the selection of the most suitable parameters for control of the analyte retention and selectivity, and therefore the choice of a better analytical assay method, in terms of the following validation parameters.

Biography

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