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E-BABE-Encyclopedia of Bioanalytical Methods for Bioavailability and Bioequivalence Studies of Pharmaceuticals - Joao Luiz - Stanford University School of Medicine

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Abstract

Encyclopedia of Bioanalytical Methods for Bioavailability and Bioequivalence Studies of Pharmaceuticals (E-BABE): It is a unique encyclopedia involving bioanalytical 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 including PubMed. This database has been curetted using published methods for all most all pharmaceuticals. Required information for regular method development/validation such as IUPAC name, structure, solubility, chromatographic conditions, instrumentation information like HPLC, LCMS detection parameters, sample preparations, recovery details, limit of detection and limit of quantification, Tmax, Cmax etc., for routine application in BA/BE studies of pharmaceuticals was incorporated including official pharmacopeias information such as European Pharmacopeia, Japan Pharmacopeia and US Pharmacopeia. Database includes drug based bioanalytical methods covering most required fields and external database links of important drug portals such as drug bank, Rxlist, MEDLINE plus, KEGG Drug ID, KEGG Compound ID, Merck manual, PubChem compound ID, PubChem substance ID and USFDA. Searching/querying the database is through drug name, chemical formula or structural search by smiles format. Keen selections of bioanalytical methods for pharmaceutical analysis or regular quality control are also possible with E-BABE. E-BABE was built understanding the needs of pharmaceutical industry and laboratories including CROs working on BA/BE studies. Presently it has nearly of 5,000 methods and it will be updated regularly. (Up to 250 words)

Only half of hypertensive patients with blood pressure ≥ 140/90 mmHg are undergoing treatment worldwide. Hypertension remains quantitatively the most important cardiovascular risk factor and is responsible for 4.4% of global mortality. It is a asymptomatic disease. So in Africa more than a halp of hypertensive patients is not diagnosed. Many patients don't go or go to hospitals very late. With the aging of the population, the increasing prevalence of obesity, sleep apnea syndrome and chronic renal failure. Etiology, the number of hypertensive patients with resistant hypertension will increase. The contributing factors of resistant hypertension identified in most cases of essential hypertension remain unclear. Today, the new suspected pathophysiological hypotheses unknown in Africa traditional medecine are: an increased sympathetic neuronal activity, an excess of activity, or an inappropriate activity of aldosterone and angiotensin II compared to sodium intakes, a congenital predisposition or developed during the fetal life (number of nephrons, birth weight, etc.), and the observation that blood pressure is approximately 30-50% hereditary. These pathophysiological causes would help in the validation of plantes used by local therapists. The objective of this work was to identify and document among medicinal hypotensive plants those which can release resistante hypertension. To achieve this objective an ethnomedical and ethnopharmacological survey was conducted nearby 1131 interviewers living in 58 socio-cultural groups random distributed in ecosystems of Cameroon. The plants identified have been subject of bibliographic research confirming their effectiveness. The ethnopharmacological mode of herbal medicines preparation and administration, the dose, the duration of treatment were also taken in consideration. Ten plants belonging to 7 families and 8 gena, were recorded. Phyllanthus amarus aqueous extract induced antihypertensive effect associated with an improved cardiac structure and calcium channel ion blockade in relaxing smooth muscle. Such a beneficial effect might involve the normalization of the level of vascular

oxidative stress. Herbal medicines which will be more effective in the management of resistant hypertension could be exploited in drugs' manufacture worldwide.

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 were 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) was 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 analytes. 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.