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Effect of Egret River tea (an antihypertensive herbal supplement tea) on the pharmacokinetic profile of oral Telmisartan in rabbits

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Drug interaction affects therapeutic actions of medicines by influencing absorption, distribution and disposition rates of drugs. This study investigated the effect of Egret River tea (an antihypertensive herbal supplement tea), on the pharmacokinetic profile of oral single dose telmisartan in rabbits. In the first phase, a dose of oral telmisartan (40 mg/kg) was administered to rabbits after overnight fast. Blood samples (3.0 ml) were drawn from an in dwelling catheter into EDTA bottles at 0.0, 0.5, 1, 2, 4, 6, 8, 10 and 24 hours. The blood samples were centrifuged at 3000 rpm for 10 minutes and plasma harvested. In the second phase, the rabbits were allowed free access to their normal feeds for two weeks. The Egret River tea (150 ml) prepared by maceration of one tea bag in hot water was administered orally for three days. The rabbits were fasted overnight after the last dose of the tea and telmisartan (40 mg/kg) was administered to the rabbits orally. Blood samples were collected and treated as earlier. Telmisartan was analyzed using UV-spectrophotometric method after liquid-liquid extraction from plasma using diethyl-ether and dichloromethane (60:40% v/v), at 238 nm. Method validation parameters found method to be efficient enough for the comparative pharmacokinetic work with linearity between 8-90 µg/ml with a correlation coefficient (r^2) of 0.994 and % recovery of 96.95% with RSD of 0.0098. Egret River tea significant ($p<0.05$) decrease Cmax, AUC0-24, AUCo-∞ and t1/2β, while there was significant ($p<0.05$) increase in Vd. However Egret River tea did not statistically ($p>0.05$) affect the Tmax, Cl/F and the t1/2α.

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Biosimilars: Latin America's coming on board regulatory approval and market access

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Biotechnological medicines are medicinal products of biotechnological origin that contain proteins derived from DNA technology. The biotechnologies use living organisms such as plant and animal cells, bacteria, viruses and yeasts for the production of medicines that includes such biological factors as cytokines, hormones, clotting factors, monoclonal antibodies, vaccines, etc. Biosimilars are attempted copies of existing biological medicinal products or protein drugs. They are made with a different cell line and a different manufacturing and purification process. Biosimilars are coming after the expiry of patent protection for many original medicines. They are considered as possible products at lower costs in comparison to modern therapies for patients and governments which are often more acceptable by patients. Less time and money is spent on clinical research for them to reach the market, as well as less pharmacovigilance. The experience with biosimilars to date is limited and long term safety and efficacy are unavailable. Immunogenicity is often unknown. Because of the above, there is need for appropriate regulations, the clear identification of potential problems and close pharmacovigilance. Latin America has become a new marketplace for the commercialization of biosimilars. However, the lack of regulations, requiring strict clinical trials and close pharmacovigilance has created Latin America an easy target for local and foreign companies to market biosimilars. As in all countries, significant clinical and non-clinical testing should be required for biosimilars to be marketed in Latin America. Substantial NDA-type dossiers should be submitted and post-market safety surveillance must be carried out. For that to occur, substantial manufacturing investments and sales promotion and marketing are required to be set in place. Latin America can certainly become a safe marketplace for biosimilars only and now that regulatory strategies are set in place and clinical and non-clinical trials are conducted with detailed pharmacovigilance before and after their marketing. The objectives of this study are: To make companies in Europe and worldwide aware that Latin America is setting down clear regulations on biosimilars; for Latin America to follow the EMA guidelines on biosimilars; and for the worldwide standardization of guidelines on biosimilars.

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