doi: 10.4172/0975-0851.1000104

Joint Meeting

2nd World Congress on Bioavailability & Bioequivalence: Pharmaceutical R & D Summit-2011

International Conference on Pharmaceutics & Novel Drug Delivery Systems

A new approach to bioequivalence studies for nasal sprays: Nasal challenge considering histamine intermediate-late phase reaction

Natalia Fabbri[1], Eduardo Abib-Jr[1,2], Bruna Sharlac Vian[1], Antonio Amarante[2] and Ricardo L Zollner[1]

[1]University of Campinas, Brazil
[2]Scentryphar Clinical Research, Brazil

Topical intranasal corticosteroids are widely recognized as the first-line anti-inflammatory treatment. Many of the most-prescribed nasal sprays containing local action drugs are expected to go off patent, with a consequent increase of the generic copies of these medications, creating greater product competition and consequently, price reduction. Bioequivalence studies for nasal sprays are still under discussion. The study designs for this purpose generally use long-term therapeutic intervention models with a high cost and long-term treatment of patients. This study was designed to demonstrate the feasibility of nasal challenge, histamine intermediate-late phase reaction and rhinomanometry in bioequivalence studies for nasal sprays. An open, randomized, crossover study, using two periods and two sequences to evaluate pharmacodynamic equivalence between two formulations of beclomethasone dipropionate spray. After nasal challenge with 0.5mg/ml histamine (previously defined), 25 healthy volunteers were submitted to an anterior rhinomanometry at the time 0; 15; 30 and 60 minutes building a baseline of flow, pressure and resistance of nasal chamber. The volunteers were then submitted to nasal drug spray Test (**T**) or Reference(**R**) of beclomethasone dipropionate, according to a randomized schedule. The Area Under Curve (AUC_{0-t}) was analyzed. The ratio between the geometrics averages of AUC_{0-t} from **T** and **R** was 1.08 for 90% CI (0.245; 0.226), suggesting the bioequivalence between formulations.

Biography

Ricardo L Zollner, Graduated in Medicine (1981); Medical Residence (1984); MsC (1987) and PhD (1990) by Faculty of Medicine, Ribeirão Preto, University of São Paulo, Ribeirão Preto, SP, Brazil. (1975-97) Post-doctoral training in the Molecular Immunopathology Unit - MIP, MRC- Cambridge, UK. Areas of Research: Allergy and Autoimmunity. Associate Professor of Immunology and Head of Postgraduate Training Program in Clinical Medicine, Faculty of Medical Sciences, University of Campinas, Campinas, SP, Brazil.