Salman Alfadhel, J Bioequiv Availab 2015, 7:5
http://dx.doi.org/10.4172/0975-0851.S1.022

OMICS International
conferenceseries.com

6th World Congress on
Bioavailability & Bioequivalence:
BA/BE Studies Summit

August 17-19, 2015 Chicago, USA

In-vitro bioequivalence study of Tiotropium bromide inhaled drug emitted from Spiriva and Tiova formulations

Salman Alfadhel
King Abdullah International Medical Research Renter, KSA

Introduction: Asthma and other pulmonary diseases are currently treated in millions of people over the world with orally inhaled drugs (OIDs). The traditional pharmacokinetic approaches (AUC and C_{max} determination) are currently not accepted by the FDA for evaluating the Inhalations drugs equivalence. The goal of the FDA solicitation (Solicitation Number: 10-223-SOL-00277, part 4) is that pharmacokinetic studies provide an indications and information's about deposition of inhaled drugs at different regional of the lung. for slowly dissolving drugs (e.g fluticasone propionate) a smaller AUC and C_{max} will be observed, if the drug is deposited more centrally, as the mucociliary clearance present in the central parts of the lung will remove a larger portion of the more centrally deposited dose, thus leading to a reduction in absorbed dose, AUC and C_{max}. Moreover, fast dissolving drugs or drugs in solution differences in C_{max} will indicate differences in the c/p ratio.

Methods: The *in-vitro* performance of delivering Tiotropium Bromide from Tiova® were compared with results obtained from Spiriva by using Next Generation Impactor (NGI) operated at different flow rate (30,40,50 and 60 L/min). The method described in the US pharamacopoeia.

Results: The Emitted dose of Spiriva at flow rate of 30, 40, 50 and 60 L/min as percentage nominal dose (SD) were 100.4 (0.2), 100.4 (0.4), 100.2 (0.2) and 100.2 (0.2) respectively. In addition, the fine particle fraction of Spiriva at same flow rate (SD) were 50.3 (2.2), 55.6 (0.7), 60.4 (1.5) and 63.3 (6.7) respectively. The mass median aerodynamic diameter of Spiriva at flow rate of 30, 40, 50 and 60 L/min were 3.3 (0.4), 2.9 (0.1), 2.4 (0.1) and 2.4 (0.1) respectively. In contrast, the Emitted dose of Tiova at flow rate of 30, 40, 50 and 60 L/min as percentage nominal dose (SD) were 100.4 (0.4), 100.2 (0.1), 100.1 (0.1) and 100.1 (0.1) respectively. The fine particle fraction of Tiova at flow rate of 30, 40, 50 and 60 L/min (SD) were 44.9 (0.7), 49.2 (1.2), 52.2 (0.7) and 49.1 (2.7) respectively. In addition, the mass median aerodynamic diameter of Spiriva at the same flow rate (SD) were 3.4 (0.1), 3.3 (0.1), 3.2 (0.1) and 3.5 (0.2) respectively.

alfadhelsa@ngha.med.sa

Notes: