allied academies

Global Summit on

BIOPHARMA & BIOTHERAPEUTICS

May 14-15, 2018 | Montreal, Canada

Challenges and bioequivalence requirements of Orally Inhaled Drug Products (OIPs) - Salmeterol xinafoate/fluticasone propionate HFA pMDI pharmacokinetic studies

Muneesh Garg
Sitec Labs Pvt. Ltd., India

Orally inhaled drug products (OIPs), such as corticosteroids and bronchodilators are most widely used for the treatment of respiratory diseases, such as asthma and chronic obstructive pulmonary disease (COPD). Salmeterol/fluticasone propionate is a fixed-dose combination inhalation agent containing a long-acting b2-adrenoceptor agonist (LABA) plus a corticosteroid and is known to be effective and well accepted in the treatment of asthma and COPD. Introducing generics of these products is essential as the pricing of these medications remains a barrier to adequate patient care. Establishing bioequivalence of OIPs is very challenging. Study procedures and bioequivalence requirements of OIPs in US, Canada and Europe will be discussed in this presentation. Four pharmacokinetic studies were conducted in healthy volunteers to determine bioequivalence of test and the reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI, two with the higher strength (25/250mcg per actuation) and two with the lower strength (25/125mcg per actuation). All the studies were single dose, randomized, crossover studies with a minimum washout period of 14 days. Two of the four studies (for each strength) also compared the pulmonary deposition by blocking gastrointestinal absorption (GI) using charcoal blockade. Since the 90% CI for Cmax and AUC0-t for both salmeterol and fluticasone were within the 80–125% interval in all the studies, it was concluded that test and the reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI were bioequivalent with and without charcoal blockade for both the strengths as per EMA guidelines.

e: muneesh.garg@siteclabs.com