Biowaiver Justification of Lower Strength Valsartan: Is There a Need For Additional Recommendations?

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Abstract

Background: Bioequivalence studies (BEs) have been widely used as 'gold standards' in proving similarities and interchangeability between innovator products and their generic versions. Unfortunately, this methodology is expensive, time-consuming and invasive to human. Therefore, the biowaiver (*in-vitro* dissolution studies) have emerged as a powerful surrogate for in-vivo bioequivalence tests. **Purpose:** The main of this study is to evaluate the biowaiver eligibility of a lower strength of valsartan as a surrogate for BE study and investigate the need for further biowaiver conditions. **Method:** An USP HPLC method was verified before being used in the analysis of valsartan (VAL) in the sample was quantified. The dissolution studies were conducted on 12 tablets (innovator and generics) using three different pH media (1.2, 4.5, and 6.8) and the similarity (f2) and dissimilarity (*f1*) factors were calculated. In addition, the other biowaiver conditions were investigated. **Conclusion:** These findings suggest that the current biowaiver criteria for lower strength VAL (80mg/tablet) could be sufficient to guarantee interchangeability between generic and brand (80mg/Tablet) without the need for BEs. Review of the manufacturing process of APIs and using a sensitive analytical method to avoid and detect toxic impurities should be included as a new biowaiver condition.

Keywords: Valsartan, Biowaiver, Bioequivalence, Interchangeability, impurities