Biowaiver studies of amlodipine (5 mg/tablet): An alternative to in vivo bioequivalence studies

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Abstract

Background:
Amlodipine is an anti hypertensive agent. According to the BCS, AM can be classified as class I, especially for 5 mg dose. Objectives: The aim of this study was to prepare a biowaiver monograph based on both literature data and in vitro testing of AM as the only API present in tablet products. This kind of studies is based on the BCS properties and the risk of waiving in vivo studies of the API.

Methods:
Literature data regarding safety, permeability & physicochemical properties of AM was collected using Pubmed & Google Scholar. In vitro testing was conducted to measure the dissolution behavior in three pH (1.2, 4.5, 6.8) media for the brand and generics. AM content was assessed using UV spectrophotometer as reported in the USP and similarity and non similarity factors were calculated.

Results:
Release of AM from generics and brand tablet products showed comparable dissolution behavior in all three recommended pH media for similarity studies. Similarity factor in three media was more than 50 and non similarity factor was less than 15 in all three media for both Amlovasc & Vascopin.

Conclusion:
Based on the current BCS-based biowaiver criteria, the in vivo bioequivalence requirements can be waived for AM (5mg/tablet).