ORIGINAL RESEARCH

Physicochemical Evaluation of Brands of Amlodipine Besylate Tablets

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ABSTRACT

Background: Hypertension is a chronic condition, and the cost of filling prescriptions has a potential of putting a financial strain on patients, hence the need for lower priced but bioequivalent generics. The Nigerian drug market is awash with generics of Amlodipine besylate, a first line drug in the treatment of hypertension, therefore, any prescribed alternative must be bioequivalent to the originator.
Objectives: This study assessed the physicochemical properties of some brands in order to predict pharmaceutical and bioequivalence and invariably, the interchangeability with the innovator brand.
Methods: Compendial parameters of average weight, friability, disintegration, drug content and dissolution profile of ten generic brands were evaluated using the United States Pharmacopeia (USP) as well as the non-official hardness test.
Results: Two brands failed the test for hardness, while still keeping to the stipulated friability limit. All the brands met the required disintegration time, irrespective of the discordance of some brands in the breaking force and friability values. All brands were found to contain between 92.00 and 103.57% (w/w) of Amlodipine besylate. Two brands failed to achieve ≥75% dissolution expected at 30 minutes and this was reflected in the low f_2 values of 35.06% and 28.73%. The dissolution curves displayed a similarity for two brands, which was also corroborated by the high percentage dissolution efficiency (DE) of 92.00%, as well as the f_1 and f_2 values, compared to the innovator brand.
Conclusion: Although the parameters used may predict therapeutic equivalence, interchangeability with the comparator brand is subject to relevant bioequivalence studies.

Keywords: Amlodipine, Dissolution profile, Dissolution efficiency, Hypertension, Disintegration