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Dissolution test and comparison of *in vitro* dissolution profiles of amlodipine tablets (reference, generic and similar) marketed in Bahia, Brazil using factorial design

Fernanda de Souza Dias [1,*], Gilmar A. de C. Teles Júnior[1], João L. S. Oliveira[1], Desirée A. Bonfim[1], Jéssica A. Santos[1], Laura B. S. Souza[1], Anderson S. de Oliveira[2] and Aníbal de Freitas Santos Júnior[1]
1) Department of Life Sciences, Bahia State University, Salvador, Bahia, Brazil, 41.150-00.
2) Department of Exacts and Earth Sciences, Bahia State University, Salvador, Bahia, Brazil, 41.150-00.
e-mail: fernanda-dias@hotmail.com

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ABSTRACT

Amlodipine, used to treat arterial hypertension[1], requires essential pharmacopoeial testing for quality assurance[2]. **Objective**: To evaluate the dissolution kinetics of amlodipine tablets. **Methods**: Tests were performed[3] (weight uniformity, friability and disintegration); a dissolution method was developed, using factorial design 2^3 (rotation, HCl concentration and medium volume); within 30 min at 37±0.5 °C and USP apparatus 2 (paddle)[4] and to validated according to RDC 166/20175[5]. **Results:** Analysis of variance (ANOVA) and Paretto (Statistica7.0) showed that variables did not significantly affect drug release; and minimum conditions (50rpm and 500mL of 0.001mol L^{-1} HCl) were used to delineate dissolution profiles (1-60min)[4] in different media: distilled water (pH = 6.03); acetate buffer (pH = 4.5) and borate buffer (pH = 8.0), with major release of amlodipine in acidic medium. Dissolution efficiencies were calculated: reference (73.6%), generic (61.3%) and similar (59.1%). **Conclusion:** Amlodipine tablets complied with pharmacopoeial tests, with method fast, linear and accurate.

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