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Comparative evaluation of weight variation, hardness, friability, disintegration, and dissolution parameters of commercially available atorvastatin tablets marketed in Galle, Sri Lanka

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Atorvastatin is a widely used lipid lowering drug. Aims of this study were to compare the physicochemical (weight variation, hardness, friability, disintegration, and dissolution) parameters of one generic (Drug A) and five brands (Drug B, C, D, E, and F) of film-coated atorvastatin 20 mg tablets available in Galle, Sri Lanka and to evaluate physicochemical parameters (PP) just (T_0) and three days (T_1) after opening the package of each sample according to the specifications given in British Pharmacopeia (BP) 2016. One way ANOVA test was used to compare the PP between brands and generic. Independent t-test was used to compare the relationship of PP, at T₀ and T₁ instances in each sample. According to the specification of BP 2016, A, B, C, D, E, and F pass the weight variation, hardness, friability, disintegration, and dissolution tests. The hardness in just after opening all brands and generic was found to be in the range of 4.669 -18.242 kPa. Drug "C" exhibited the highest disintegration time (6.01 min) and Drug "B" showed the lowest disintegration time (2.44 min). When comparing the PP between brands and generic there was no significant difference (p<0.05) among them. Among T₀ and T_1 instances, all samples showed no significant difference (p<0.05) for the tested PP. This study revealed that there was no significant difference of tested physicochemical parameters between generic and brands as well among just after opening and three days after opening the package of atorvastatin 20 mg tablets.

Key words: Atorvastatin, brands, generic, physicochemical parameters

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