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Quality evaluation of different brands of Atorvastatin tablets available in Sri Lanka

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Atorvastatin is one of the mostly used statins in treating atherosclerosis. The substandard quality of generic medicines affects their therapeutic efficacy resulting in treatment failure. There are several generics of Atorvastatin available in Sri Lanka. In this study, quality of different brands of Atorvastatin (10 mg tablets) was evaluated using four pharmacopoeial tests such as uniformity of content, friability, weight variation and dissolution test. Uniformity of content of tablets were evaluated by Reversed-phase High-Performance Liquid Chromatography method (RP-HPLC). Other quality tests also were evaluated according to British pharmacopeial specifications. Mostly available fifteen brands of Atorvastatin were selected for the study from total of 21 brands of Atorvastatin. Atorvastatin tables were purchased from pharmacies in the Jaffna municipality area and evaluated for their quality. All brands were coded from S1 to S15. Descriptive statistics was used for data analysis with the help of MS Excel software. According to quality analysis, all the brands passed the friability test. Two brands (S1 and S15) were failed in uniformity of content in which S1 brand had 93% of drug and S15 brand had 107.27% of drug. Also, S15 failed in weight variation test and its weight variation was 6.7943%. S8 failed in the dissolution test in which it released only 68.067±1.50 % at the end of 45 minutes. Out of fifteen brands, three brands failed at least in one pharmacopeial test. Regulatory authorities should strictly monitor the quality of brands that are available in Sri Lanka.

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