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Study of physico-chemical parameters of atorvastatin tablets in Sri Lankan market

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Atorvastatin calcium (ATV-Ca) is a synthetic lipid lowering drug which belongs to statin group. It is most commonly prescribed for the treatment of hyperlipidemia and cardiovascular diseases. ATV-Ca is an inhibitor of 3-hydroxy-3-methylglutaryl-Coenzyme A (HMG-CoA) reductase. There are five brands of ATV-Ca available in the Sri Lankan market. However there is a huge price variation among these brands. But each and every brand exactly consists of the same dosage, therapeutic effect, safety and strength as the original drug. This study assesses in-vitro quality control tests and impurity profile of five brands of ATV-Ca available in the Sri Lankan market. All tests viz: uniformity of weight, disintegration, hardness and friability were carried out according to the British Pharmacopoeia, Indian Pharmacopoeia and United State Pharmacopoeia. Each brand of ATV-Ca tablets (Atorva, Atocor, Aztor, Atorlip and SPC) were collected in authorized pharmacies in Kegalle, Peradeniya and Kandy. Assay test and analysis of impurity profile for each brand of ATV-Ca were carried out by HPLC method. The absorbance of the solution of the tablet was measured by UV-VIS spectrometer at 246 nm wavelength. According to the assay test, all brands except brand E are in acceptable range (90%-110%: IP 2010). Minor impurities were only in brand D and E with impurity profile analysis. There is no significant difference between friability, hardness and uniformity of weight of all brands. In the disintegration test, the highest disintegration time (7.27 min) was observed for sample B, and the minimum disintegration time (3.38 min) was reported for sample A tablets. All the samples passed the BP specifications for disintegration rate test, indicating that all the disintegration times were within the BP limit of 30 minutes. In acid test, brand A showed the highest degradation. Degradation of other brands in their descending order were; D=E>B>C. In base test, brand D showed the highest degradation and brand C showed the lowest degradation with pH 13. In thermal stability test, brand D showed the highest degradation and brand C showed the lowest degradation. According to the USP specified limitations, all brands except sample C were degraded when the UV radiation was introduced. The highest degraded brand was E. According to the assay test for Atorvastatin content, brand E was not in the acceptable range and brands D and E also showed minor impurities. According to the Pharmacopoeia standards, brands D and E were not in acceptable range in quality assessment tests. So their therapeutic values may lower than other brands of ATV-Ca.