STUDY OF PHYSICOCHEMICAL 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 frequently 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. But there is a huge price variation among the considered five (05) samples of ATV Ca tablets. Each and every brand needs to have exactly the same dosage, effects, route of administration, safety, and strength as the original drug. In 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 were carried out according to the British Pharmacopoeia (2012), Indian Pharmacopoeia and United State Pharmacopoeia. Standard ATV Ca powder was received as a gift sample from Astron pvt Ltd (Rathmalana, Sri Lanka). Different brands of ATV Ca tablet (Atorva®, Atocor®, Aztor®, Atorlip®, and SPC) available in Sri Lanka were collected in Kegalle. The absorbance of the solution of the tablet and the standard was measured by UV-VIS spectrophotometer at 246 nm wavelength. Except the assay test all brands comply the limits and the guidelines of weight, hardness, disintegration and degradation tests provided by the BP (2012). According to the assay test, except brand "D" all other brands were out of specification (95% to 105%) in UV spectroscopic assay method. According to the dissolution test which was carried out at three (03) various pH values (pH 1,4.5 and 6.8) it was pointed out within the low acidic medium, brand "C" showed rapid dissolution and brand "A" showed poor dissolution. Once the level of acidity was decreased brand "C" showed poor dissolution and brand "E" showed rapid dissolution. HPLC analysis was carried out in order to identify the impurities of each sample. Minor impurities were found only in brand "D" and "E". Further HPLC/MS have to be conducted to identify the structures of the impurity chemical entities.