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DEVELOPMENT AND VALIDATION OF H-POINT STANDARD ADDITION METHOD APPLIED FOR THE ANALYSIS OF BINARY MIXTURE OF AMLODIPINE AND ATORVASTATIN

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ABSTRACT

Simple, specific, accurate and precise spectrophotometric method was developed for the simultaneous determination of Amlodipine besylate (AML) and Atorvastatin calcium (ATV) in tablet dosage forms. The proposed H-Point Standard Addition Method (HPSAM) involves addition of the analyte of interest on the binary mixture, measuring the absorbance at two wavelengths and then the calibration curves are used to estimate the concentration of the main analyte and interfernt one. Two analytical wavelengths selected were 241.0-252.4 nm and 278.0-305.6 nm for the estimation of AML and ATV; respectively. The calibration curves were linear over the concentration range of 4-40 and 8-32 µg/mL for AML and ATV, respectively. This method was tested by analyzing synthetic mixtures of the above drugs and they were applied to commercial pharmaceutical preparation of the subjected drugs. The standard deviation was < 1.5 in the assay of raw materials and tablets. Methods were validated as per ICH guidelines and accuracy, precision, repeatability and robustness were found to be within the acceptable limit.

KEY WORDS: **Spectrophotometry; H-Point; standard addition; Atorvastatin; Amlodipine.**

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