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Three different methods for determination of binary mixture of Amlodipine and Atorvastatin using dual wavelength spectrophotometry

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HIGHLIGHTS

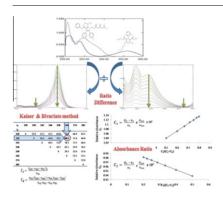
- Simple, accurate, selective and precise spectrophotometric methods.
- Collecting & comparing different methods handling dual wavelength spectrophotometry.
- ► Introducing and application of the new and simple Ratio Difference method.
- Rapid methods without need for sophisticated instruments or expensive solvents.
- Methods validated as per ICH guidelines, parameters found to be within the limits.

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ABSTRACT

Three simple, specific, accurate and precise spectrophotometric methods depending on the proper selection of two wavelengths are developed for the simultaneous determination of Amlodipine besylate (AML) and Atorvastatin calcium (ATV) in tablet dosage forms. The first method is the new Ratio Difference method, the second method is the Bivariate method and the third one is the Absorbance Ratio method. The calibration curve is linear over the concentration range of 4–40 and 8–32 μ g/mL for AML and ATV, respectively. These methods are tested by analyzing synthetic mixtures of the above drugs and they are applied to commercial pharmaceutical preparation of the subjected drugs. Methods are validated according to the ICH guidelines and accuracy, precision, repeatability and robustness are found to be within the acceptable limit. The mathematical explanation of the procedures is illustrated.

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Introduction

Amlodipine (AML), 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine carboxylic acid 3-ethyl 5-methyl ester) [1] Fig. 1a, is a dihydropyridine derivative with

calcium antagonist activity. It is used in the treatment of hypertension and chronic stable angina pectoris [2].

Atorvastatin (ATV), $[R-(R^*,R^*)]-2-(4-\text{fluorophenyl})-\beta,\delta-\text{dihydroxy-5-}(1-\text{methylethyl})-3-\text{phenyl-4-}[(\text{phenylamino})\text{carbonyl}]-1$ *H*-pyrrole-1-heptanoic acid [1], Fig. 1b, is a selective, competitive inhibitor of HMG-CoA reductase enzyme. It is used to reduce LDL-cholesterol, apolipoprotein B, and triglycerides and to increase ATL-cholesterol in the treatment of hyperlipidaemias [3].

Caduet[®] is a dosage form that has been launched by Pfizer Ltd. for the simultaneous treatment of hypertension and dyslipidaemia [4]. Caduet[®] contains both AML for the treatment of high blood

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