RESEARCH ARTICLE

STABILITY-INDICATING UV-VIS SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ATORVASTATIN CALCIUM AND FENOFIBRATE IN TABLET DOSAGE FORM

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The present research works discuss the development of a stability-indicating UV spectrophotometric method for the estimation of Atorvastatin calcium (ATC) and Fenofibrate (FEN) in tablet dosages form. The optimum conditions for the analysis of the drug were established. The maximum wavelength (λ_max) was found to be 247 nm for ATC and 287 nm for FEN. The linearity of the proposed method was investigated in the range of 6-16 µg/ml and 2-12 µg/ml for ATC, FEN respectively. Calibration curves showed a linear relationship between the absorbance and concentration. The line equation for ATC (y = 0.041x + 0.043) with r² of 0.999 and for Fenofibrate (y = 0.054x - 0.003) with r² of 0.999, was obtained. Validation was performed as per ICH guidelines for linearity, accuracy, precision, LOD and LOQ. The LOD was 0.2695 µg/ml, 0.0222 µg/ml for ATC and FEN and the LOQ was 0.8780 µg/ml, 0.222 µg/ml for ATC and FEN respectively. The proposed method may be suitable for the analysis of ATC and FEN in tablet formulation for quality control purpose. The proposed methods were simple, sensitive, precise, accurate, quick and useful for routine quality control. The stability studies of ATC and FEN were conducted and the degradation characteristics were found to be much more prominent in acid hydrolysis in FEN and alkaline hydrolysis in ATC.

Key words: Simultaneous equation, Degradation, Validation, Atorvastatin calcium, Fenofibrate.

INTRODUCTION

Atorvastatin Calcium (ATC) (Figure 1) is calcium salt of (βR, 8R)-2-(4-fluorophenyl)-α,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid trihydrate (IP 2007). ATC is a member of the drug class known as statins, used for lowering blood cholesterol. Atorvastatin works by inhibiting HMG-CoA reductase, an enzyme found in liver tissue that plays a key role in production of cholesterol in the body.

Fenofibrate (FEN) (Figure 1) is 2-[4-(4-chlorobenzoyl)phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester (ChemSpider, 3222) which is a fibric acid derivative that lowers lipid levels by activating PPARα and thus, decreases the risk of heart diseases and prevent strokes.

Atherosclerotic vascular disease is a condition in which an artery wall thickens as a result of accumulation of fatty materials such as cholesterol. It affects mostly arterial blood vessels. Inflammatory response in walls of arteries is commonly referred to as hardening of