

RESEARCH ARTICLE

STABILITY-INDICATING RP-HPLC METHOD FOR ESTIMATION OF ATORVASTATIN CALCIUM IN SOLID DOSAGE FORM

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In present investigation, a stability indicating RP-HPLC method for estimation of Atorvastatin calcium in solid dosages form is developed and validated. The chromatographic separation was achieved on Phenomenax Luna C₁₈ (50 × 4.6 mm, 5 μm) column using a mobile phase consisting of methanol:acetonitrile:water in the ratio of 70:20:10 % v/v, at a flow rate of 1.0 ml/min and UV detection at 256 nm. The linearity of the proposed method for Atorvastatin Calcium was 2-10 μg/ml (r²= 0.999) and retention time for Atorvastatin calcium was found to be 1.9223. The method was validated for accuracy, repeatability, reproducibility, robustness and system suitability. LOD and LOQ of Atorvastatin calcium were found to be 1.218 μg/ml and 4.060 μg/ml respectively. The stability studies of Atorvastatin calcium were conducted and the degradation characteristics were found to be much more prominent in alkaline hydrolysis (alkaline stress condition).

Key words: Atorvastatin calcium, RP-HPLC, Stability-indicating assay, Validation.

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. ATC is a HMG CoA reductase inhibitor, a member of the drug class known as statins which is commonly used for lowering blood cholesterol (IP, 2007; Jadhav *et al* 2010). Atherosclerotic Vascular disease is a condition in which there is an artery wall thickness as a result of accumulation of fatty materials such as cholesterol. It affects mostly arterial blood vessels, inflammatory response in walls of arteries commonly referred to as hardening of arteries. It is caused by formation of multiple plaques with in arteries. Drugs like Atorvastatin calcium has a highly beneficial effect on all lipid

parameters and is more effective in reduction of cholesterol level (EP, 2005; Jat *et al* 2012).

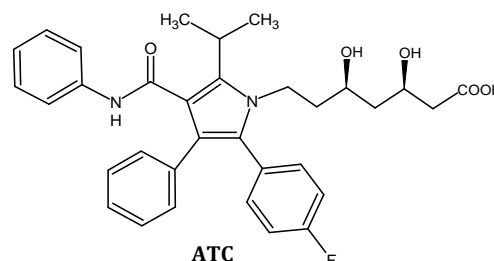


Fig. 1. Chemical structure of Atorvastatin calcium (ATC)

Safety and efficacy of pharmaceuticals are two fundamental issues of importance in drug therapy. Instability of pharmaceuticals can cause a change in physical, chemical, pharmacological