ABSTRACT

A simple, precise, sensitive and validated reverse-phase high performance liquid chromatographic (RP-HPLC) method was developed for the simultaneous determination of lovastatin and ezetimibe in human plasma using gemfibrozil as an internal standard (IS). The assay procedure involved protein precipitation and extraction of ezetimibe, lovastatin and IS from plasma into acetonitrile , the drugs were reconstituted in mobile phase and were separated on a 250*4.6, 5µ Merck C-18 column. Eluents were monitored at a wavelength of 240 nm using diode array detector with a mobile phase consisting of a mixture of 0.1M ammonium acetate buffer pH 5.0 and acetonitrile in the ratio of (30:70, v/v). The linearity was observed in the concentration range of 0.4-500 µg/ml for lovastatin and 0.2-250 µg/ml for ezetimibe with correlation coefficient between 0.9911 and 0.9958. The lower limit of detection was 0.12 µg/ml for lorvastatin and 0.06 µg/ml for ezetimibe. The limit of quantitation was 0.4 µg/ml for lorvastatin and 0.2 µg/ml for ezetimibe. The recovery was greater than 95% for ezetimibe, lovastatin and gemfibrozil with RSD less than 6 %. The total run time was less than eleven minutes for the two components. The proposed method was validated by testing its linearity, recovery, specificity, repeatability, LOD/LOQ values and it was successfully employed for the determination of lovastatin and ezetimibe in human plasma.