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Determination of Atorvastatin and Gemfibrozil in Human Plasma by Reversed-Phase Liquid Chromatography

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SUMMARY. A simple, sensitive and reproducible RP-HPLC method was developed and validated for the simultaneous determination of atorvastatin and gemfibrozil in human plasma. After a single step liquid-liquid extraction of both the drugs with acetonitrile, the separation was accomplished on a Merck C 18 column (250 x 4.6, 5 μ m). Diode array detection at a wavelength of 240 nm was carried out with a mobile phase comprising of a mixture of 0.1M ammonium acetate buffer (pH 5.0) and acetonitrile in the ratio of (45:55, v/v). The method was linear in the concentration range of 0.1-20 μ g/ml for atorvastatin and 6-1200 μ g/ml for gemfibrozil with correlation coefficient between 0.9997 and 0.9976. The limit of detection was 0.03 μ g/ml for atorvastatin and 1.8 μ g/ml for gemfibrozil. The limit of quantitation was 0.1 μ g/ml for atorvastatin and 6 μ g/ml for gemfibrozil. The average recovery of both the analytes was greater than 75 %. The method was validated in terms of linearity, recovery, precision, specificity, LOD/LOQ values and stability of solutions and it was applied successfully for the determination of atorvastatin and gemfibrozil in spiked human plasma.

KEY WORDS: Atorvastatin, Diode array detector, Gemfibrozil, HPLC, plasma.

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