Development of a Liquid Chromatographic Method for Bioanalytical Applications with Sildenafil

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Abstract

An improved HPLC method was developed for the determination of sildenafil concentrations in plasma. Analysis of sildenafil in plasma samples was simplified by utilizing a one-step liquid-liquid extraction after alkaline treatment of only 1 ml of plasma. The lower limit of quantitation was 10 ng/ml with a coefficient of variation of less than 20%. A linear range was found to exist from 10 to 1000 ng/ml. This HPLC method was validated with precisions (coefficient of variation, C.V.) for inter- and intra-day runs of 0.41-11.15% and 0.36-8.05%, respectively, and accuracies (the relative error of the mean, REM) for inter- and intra-day runs of -8.72-6.81% and 0.41-11.15%, respectively. A bioavailability study of sildenafil was performed on one normal healthy male volunteer by analyzing sildenafil plasma concentrations with this validated HPLC method. Results demonstrated that this HPLC method is appropriate for applications to bioavailability studies of sildenafil. In addition, an example of the influence of the co-administration of grapefruit juice on sildenafil pharmacokinetics in a healthy volunteer is presented.