

SIMULTANEOUS DETERMINATION OF STAVUDINE AND LAMIVUDINE IN HUMAN PLASMA BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY AND ITS APPLICATION TO A BIOAVAILABILITY STUDY

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Abstract. A high performance liquid chromatographic method with UV detection was developed and validated for simultaneous determination of stavudine and lamivudine in human plasma using solid-phase extraction for sample clean-up. Zidovudine was used as an internal standard. Separation was performed on a C18 column by gradient elution with a mobile phase of 10 mM acetate buffer pH 6.5 and acetonitrile. The UV detection was set at 265 nm. The method proved to be specific, accurate, precise and linear over the concentration ranges of 50-3,000 ng/ml for stavudine and 50-5,000 ng/ml for lamivudine with correlation coefficients always >0.996 for both drugs. The intra-day and inter-day precision and accuracy were less than 9.2% for both analytes. The absolute recoveries of both compounds ranged from 93.3 to 97.5%. The method was successfully applied to a bioavailability study of a combined tablet formulation containing 30 mg of stavudine and 150 mg of lamivudine compared with each reference formulation concurrently administered in 26 healthy Thai male volunteers.

Key words: stavudine, lamivudine, HPLC-UV method, bioavailability

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