A single-dose, randomized, open-label, two-period crossover bioequivalence study comparing a fixed-dose pediatric combination of lamivudine and stavudine tablet for oral suspension with individual liquid formulations in healthy adult male volunteers.
stavudine were assayed using validated high-performance liquid chromatography with mass spectrometry analytical method. Pharmacokinetic parameters were calculated using non-compartmental analysis and bioequivalence was assessed using a mixed effect ANOVA model. The ratio of the least-square means (FDC to individual products) and 90% confidence intervals (CIs) of AUC(0-t), AUC(0-infinity) and C(max) for lamivudine and stavudine were all within 80.00-125.00%, suggesting a similar rate and extent of ARVs exposure in the bloodstream. The FDC and individual products were equally safe and well tolerated. The current FDC of lamivudine and stavudine is expected to provide a similar efficacy/safety profile as co-administration of the individual products, a better adherence to treatment, and considerable cost savings in the treatment of HIV in children.