A new and simple HPLC method was developed and validated for the determination of etamsylate in human plasma and its application to pharmacokinetic study in healthy adult male volunteers.

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Abstract
A new and simple HPLC assay method was developed and validated for the determination of etamsylate in human plasma. After protein precipitation with 6% perchloric acid, satisfactory separation was achieved on a HyPURITY C18 column (250 mm X 4.6 mm, 5μm) using a mobile phase comprised 20 mM sodium dihydrogen phosphate-2 hydrate (pH was adjusted to 3.5 by phosphoric acid) and acetonitrile at a ratio of 95:5 v/v. The elution was isocratic at ambient temperature with a flow rate of 0.75 ml/min. Allopurinol was used as internal standard. The calibration curve was linear over the range from 0.25 to 20 μg/ml \( r^2 = 0.999 \). The limit of quantification for etamsylate in plasma was 0.25 μg/ml. The day-to-day coefficient of variance (%CV) ranged from 3.9% to 10.2 %, whereas
The between-days %CV ranged from 3.1% to 8.7%. The assay method has been successfully used to estimate the pharmacokinetics of etamsylate after oral administration of a 500 mg tablet under fasting conditions to 24 healthy Egyptian human male volunteers. Various pharmacokinetic parameters including AUC0–t, AUC0–∞, Cmax, Tmax, t1/2, MRT, Cl/F, and Vd/F were determined from plasma concentration-time profile of etamsylate.

Keywords: Etamsylate; HPLC; validation; plasma; pharmacokinetics

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